

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 20-F

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

For the fiscal year ended December 31, 2018

Commission File No.: 001-37846

CELLECT BIOTECHNOLOGY LTD.
(Exact name of registrant as specified in its charter)

Translation of registrant's name into English: Not applicable

State of Israel

(Jurisdiction of incorporation or organization)

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(Address of principal executive offices)

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

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

Title of each class to be registered

**Name of each exchange on which each class
is to be registered**

American Depositary Shares, each representing twenty (20) Ordinary Shares,
no par value per share

The Nasdaq Stock Market LLC

Warrants to purchase American Depositary Shares

The Nasdaq Stock Market LLC

Ordinary Shares, no par value per share*

N/A

* Not for trading, but only in connection with the registration of the American Depositary Shares pursuant to requirements of the Securities and Exchange Commission.

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

Number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2018: 130,414,799 ordinary shares.

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

Yes No

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

Yes No

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

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months.

Yes No

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

Large accelerated filer Accelerated filer Non-accelerated filer
Emerging Growth Company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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

U.S. GAAP

International Financial Reporting Standards as issued by the International Accounting Standards Board

Other

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

Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company.

Yes No

TABLE OF CONTENTS

	Page
<u>INTRODUCTION</u>	iii
<u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	iii
<u>PART I</u>	
ITEM 1. <u>IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS</u>	1
ITEM 2. <u>OFFER STATISTICS AND EXPECTED TIMETABLE</u>	1
ITEM 3. <u>KEY INFORMATION</u>	1
A. <u>Selected Financial Data</u>	1
B. <u>Capitalization and Indebtedness</u>	2
C. <u>Reasons for the Offer and Use of Proceeds</u>	2
D. <u>Risk Factors</u>	2
ITEM 4. <u>INFORMATION ON THE COMPANY</u>	21
A. <u>History and Development of the Company</u>	21
B. <u>Business Overview</u>	22
C. <u>Organizational Structure</u>	52
D. <u>Property, Plants and Equipment</u>	52
ITEM 4A. <u>UNRESOLVED STAFF COMMENTS</u>	52
ITEM 5. <u>OPERATING AND FINANCIAL REVIEW AND PROSPECTS</u>	53
A. <u>Operating Results</u>	53
B. <u>Liquidity and Capital Resources</u>	57
C. <u>Research and Development, Patents and Licenses</u>	59
D. <u>Trend Information</u>	60
E. <u>Off-Balance Sheet Arrangements</u>	60
F. <u>Tabular Disclosure of Contractual Obligations</u>	60
ITEM 6. <u>DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES</u>	60
A. <u>Directors and Senior Management</u>	60
B. <u>Compensation</u>	63
C. <u>Board Practices</u>	66
D. <u>Employees</u>	77
E. <u>Share Ownership</u>	77
ITEM 7. <u>MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS</u>	78
A. <u>Major Shareholders</u>	78
B. <u>Related Party Transactions</u>	81
C. <u>Interests of Experts and Counsel</u>	82
ITEM 8. <u>FINANCIAL INFORMATION</u>	82
A. <u>Consolidated Statements and Other Financial Information</u>	82
B. <u>Significant Changes</u>	82
ITEM 9. <u>THE OFFER AND LISTING</u>	82
A. <u>Offer and Listing Details</u>	82
B. <u>Plan of Distribution</u>	82
C. <u>Markets</u>	82
D. <u>Selling Shareholders</u>	82
E. <u>Dilution</u>	82
F. <u>Expenses of the Issue</u>	83

ITEM 10.	<u>ADDITIONAL INFORMATION</u>	83
A.	<u>Share Capital</u>	83
B.	<u>Articles of Association</u>	83
C.	<u>Material Contracts</u>	87
D.	<u>Exchange Controls</u>	89
E.	<u>Taxation</u>	89
F.	<u>Dividends and Paying Agents</u>	96
G.	<u>Statement by Experts</u>	96
H.	<u>Documents on Display</u>	96
I.	<u>Subsidiary Information</u>	96
ITEM 11.	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	97
ITEM 12.	<u>DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES</u>	97
A.	<u>Debt Securities</u>	97
B.	<u>Warrants and rights</u>	97
C.	<u>Other Securities</u>	97
D.	<u>American Depositary Shares</u>	98
 <u>PART II</u> 		
ITEM 13.	<u>DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES</u>	99
ITEM 14.	<u>MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS</u>	99
ITEM 15.	<u>CONTROLS AND PROCEDURES</u>	99
ITEM 16A.	<u>AUDIT COMMITTEE FINANCIAL EXPERT</u>	100
ITEM 16B.	<u>CODE OF ETHICS</u>	100
ITEM 16C.	<u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	100
ITEM 16D.	<u>EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES</u>	101
ITEM 16E.	<u>PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS</u>	101
ITEM 16F.	<u>CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT</u>	101
ITEM 16G.	<u>CORPORATE GOVERNANCE</u>	101
ITEM 16H.	<u>MINE SAFETY DISCLOSURE</u>	102
 <u>PART III</u> 		
ITEM 17.	<u>FINANCIAL STATEMENTS</u>	103
ITEM 18.	<u>FINANCIAL STATEMENTS</u>	103
ITEM 19.	<u>EXHIBITS</u>	103
	<u>SIGNATURES</u>	106

INTRODUCTION

We are an emerging biotechnology company that has developed a novel technology platform known as ApoGraft that functionally selects stem cells in order to improve the safety and efficacy of regenerative medicine and stem cell therapies. We aim to become the standard enabling technology for the enrichment of the stem cell population for companies developing stem cell therapies, for physicians practicing regenerative medicine and for researchers and academia engaged in stem cell research.

On July 29, 2016, our American Depositary Shares, or ADSs, each representing twenty of our ordinary shares, and our listed warrants, commenced trading on the Nasdaq Capital Market under the symbols “APOP” and “APOPW”, respectively. From 1990 to September 3, 2017, our shares were traded on the Tel Aviv Stock Exchange, or the TASE.

Unless otherwise indicated, all references to the terms “we”, “us”, “our”, “Collect”, “the Company” and “our Company” refer to Collect Biotechnology Ltd. and its wholly owned subsidiaries. References to “ordinary shares”, “ADSs”, “warrants” and “share capital” refer to the ordinary shares, ADSs, warrants and share capital, respectively, of Collect.

References to “U.S. dollars” and “\$” are to currency of the United States of America, and references to “NIS” are to New Israeli Shekels. References to “ordinary shares” are to our ordinary shares, no par value. We report financial information under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or the IASB, and none of the financial statements were prepared in accordance with generally accepted accounting principles in the United States.

Unless otherwise indicated, U.S. dollar translations of NIS amounts presented in this annual report on Form 20-F for the year ended on December 31, 2018 are translated using the rate of NIS 3.748 to \$1.00, the exchange rate reported by the Bank of Israel on December 31, 2018; U.S. dollar translations of NIS amounts presented in this annual report on Form 20-F for the year ended on December 31, 2017 are translated using the rate of NIS 3.467 to \$1.00, the exchange rate reported by the Bank of Israel on December 31, 2017; and U.S. dollar translations of NIS amounts presented in this annual report on Form 20-F for the year ended on December 31, 2016 are translated using the rate of NIS 3.845 to \$1.00, the exchange rate reported by the Bank of Israel on December 31, 2016.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain information included or incorporated by reference in this annual report on Form 20-F may be deemed to be “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws. Forward-looking statements are often characterized by the use of forward-looking terminology such as “may,” “will,” “expect,” “anticipate,” “estimate,” “continue,” “believe,” “should,” “intend,” “project” or other similar words, but are not the only way these statements are identified.

These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, statements that contain projections of results of operations or of financial condition, expected capital needs and expenses, statements relating to the research, development, completion and use of our products, and all statements (other than statements of historical facts) that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things:

- our history of losses and needs for additional capital to fund our operations and our inability to obtain additional capital on acceptable terms, or at all;
- our ability to continue as a going concern;

- uncertainties of cash flows and inability to meet working capital needs;
- our ability to obtain regulatory approvals;
- our ability to obtain favorable pre-clinical and clinical trial results;
- our technology may not be validated and our methods may not be accepted by the scientific community;
- difficulties enrolling patients in our clinical trials;
- the ability to timely source adequate supply of Fas ligand;
- risks resulting from unforeseen side effects;
- our ability to establish and maintain strategic partnerships and other corporate collaborations;
- the scope of protection we are able to establish and maintain for intellectual property rights and our ability to operate our business without infringing the intellectual property rights of others;
- competitive companies, technologies and our industry;
- unforeseen scientific difficulties may develop with our technology;
- our ability to retain or attract key employees whose knowledge is essential to the development of our products; and
- those factors referred to in “Item 3. Key Information—D. Risk Factors,” “Item 4. Information on the Company,” and “Item 5. Operating and Financial Review and Prospects”, as well as in this annual report on Form 20-F generally.

Readers are urged to carefully review and consider the various disclosures made throughout this annual report on Form 20-F which are designed to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

You should not put undue reliance on any forward-looking statements. Any forward-looking statements in this annual report on Form 20-F are made as of the date hereof, and we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, the section of this annual report on Form 20-F entitled “Item 4. Information on the Company” contains information obtained from independent industry sources and other sources that we have not independently verified.

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 selected consolidated financial data for the fiscal years set forth in the table below have been derived from our consolidated financial statements and notes thereto. The selected consolidated statements of comprehensive loss data for the years ended December 31, 2016, 2017 and 2018, and the selected consolidated balance sheet data at December 31, 2017, and 2018, have been derived from our audited consolidated financial statements and notes thereto set forth elsewhere in this annual report on Form 20-F. The selected consolidated statements of comprehensive loss data for the years ended December 31, 2014 and 2015, and the selected consolidated balance sheet data as of December 31, 2014, 2015 and 2016, have been derived from our audited consolidated financial statements not included in this annual report on Form 20-F. The selected financial data should be read in conjunction with our consolidated financial statements, and are qualified entirely by reference to such consolidated financial statements.

Consolidated Statements of Comprehensive Loss Data

	Year ended December 31,					Convenience translation(2) Year ended December 31, 2018
	2014	2015	2016	2017	2018	U.S. dollars in thousands
	NIS in thousands except shares and share data					
Research and development expenses, net	3,058	5,893	8,256	11,503	13,513	3,605
General and administrative expenses	2,491	4,204	7,968	12,930	15,734	4,198
Other income	-	-	(280)	-	-	-
Total operating expenses	5,549	10,097	15,944	24,433	29,247	7,803
Operating loss	5,549	10,097	15,944	24,433	29,247	7,803
Financial income	(37)	(4)	(660)	(101)	(9,154)	(2,442)
Financial expenses	39	79	33	3,892	20	6
Net loss	5,551	10,172	15,317	28,224	20,113	5,367
Total comprehensive loss	5,551	10,172	15,317	28,224	20,113	5,367
Loss per share						
Basic and diluted loss per share (1)	0.084	0.137	0.168	0.252	0.155	0.041
Basic and diluted loss per ADS	1.68	2.74	3.36	5.04	3.11	0.82
Weighted average number of shares outstanding used to compute basic and diluted loss per share	65,968,768	74,475,109	91,128,516	111,968,663	129,426,091	129,426,091

Consolidated Balance Sheet Data

	Year ended December 31,					Convenience translation(2) Year ended December 31, 2018
	2014	2015	2016	2017	2018	U.S. dollars in thousands
	NIS in thousands					
Cash and cash equivalents	2,122	3,913	6,279	13,734	17,809	4,752
Short term deposits	-	-	19,660	-	-	-
Marketable securities	11,257	7,829	4,997	13,999	-	-
Other receivables	161	412	1,461	818	816	218
Restricted cash	20	20	140	305	337	90
Other long term receivables	-	-	-	173	132	35
Property, plant and equipment	234	1,187	1,373	1,344	1,544	412
Total assets	13,794	13,361	33,910	30,373	20,638	5,507
Trade payable	107	466	1,401	1,703	887	237
Other payables	728	2,394	2,084	2,396	4,012	1,070
Warrants to ADS	-	-	1,938	7,422	1,816	485
Total liabilities	835	2,860	5,423	11,521	6,715	1,792
Loan from controlling shareholder	-	-	-	-	-	-
Total shareholders' equity	12,959	10,501	28,487	18,852	13,923	3,715

(1) Data on diluted loss per share were not presented separately in the financial statements because the effect of the exercise of the options and warrants is anti-dilutive.

(2) Calculated using the exchange rate reported by the Bank of Israel for December 31, 2018 at the rate of one U.S. dollar to NIS 3.748.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks described below, together with all of the other information in this annual report on Form 20-F. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business operations. If any of these risks actually occurs, our business and financial condition could suffer and the price of our ADSs could decline.

Risks Related to Our Financial Position and Capital Requirements

We are an early stage company with a limited operating history.

Our wholly-owned subsidiary commenced operations developing our functional stem cell selection ApoGraft technology in 2011. As such, we have a limited operating history and our operations are subject to all of the risks inherent in the establishment of a new business enterprise, including a lack of operating history. We cannot be certain that our business strategy will be successful or that we will be solvent at any particular time. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with the establishment of any company. If we fail to address any of these risks or difficulties adequately, our business will likely suffer. Because of the numerous risks and uncertainties associated with developing and commercializing our ApoGraft technology platform, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the attempted development and commercialization of procedures and products in the medical, cell therapy, biotechnology and biopharmaceutical industries. We may never successfully commercialize ApoGraft and our business may fail.

We have a history of losses and can provide no assurance of our future operating results.

Since 2011, we have been focused on research and development activities with a view to developing our ApoGraft technology platform. We have financed our operations primarily through the sale of equity securities (both in private placements and in public offerings on the TASE and also on the Nasdaq) and have incurred losses in each year since our inception. We have historically incurred substantial net losses, including net losses of approximately NIS 20.1 million (\$5.3 million) in 2018, NIS 28.2 million (\$8.1 million) in 2017, and NIS 15.3 million (\$4.0 million) in 2016. As of December 31, 2018, we had an accumulated deficit of approximately NIS 84.1 million (\$22.4 million). We do not know whether or when we will become profitable. To date, we have not commercialized our technology or generated any revenues and accordingly we do not have a revenue stream to support our cost structure. Our losses have resulted principally from costs incurred in development and discovery activities. The opinion of our independent registered public accounting firm on our audited financial statements as of and for the year ended December 31, 2018 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we:

- initiate and manage preclinical development and clinical trials for our ApoGraft technology platform and ApoTainer kit;
- implement internal systems and infrastructures;
- seek to license additional technologies to develop;
- hire management and other personnel; and
- move towards commercialization.

We will need significant additional capital, which we may be unable to obtain. If we are unable to raise capital, we will be forced to reduce or eliminate our operations.

As of December 31, 2018, we had approximately NIS 17.8 million (\$4.8 million) in cash and cash equivalents, a working capital of NIS 13.7 million (\$3.7 million) and an accumulated deficit of NIS 84.1 million (\$22.4 million). Based on our current cash balances, our management is of the opinion that without fund raising we have sufficient capital to finance our operations until the end of the first quarter of 2020. We will need to raise significant additional capital, in one or more financings, and if we are unable to obtain additional sufficient financing, we will be forced to reduce the scope of, or eliminate our operations which would have a materially adverse effect on our business and results of operations.

Since our inception, most of our resources have been dedicated to the development of ApoGraft. In particular, we have expended and believe that we will continue to expend significant operating and capital expenditures for the foreseeable future developing our ApoGraft technology platform and our ApoTainer collection kits. These expenditures will include, but are not limited to, costs associated with research and development, manufacturing, conducting preclinical experiments and clinical trials, contracting manufacturing organizations, hiring additional management and other personnel and obtaining regulatory approvals, as well as commercializing any products approved for sale. Furthermore, we expect to incur additional costs associated with operating as a public company in the United States. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our ApoGraft technology platform, our ApoTainer collection kits and any other future product. In addition, other unanticipated costs may arise. As a result of these and other factors currently unknown to us, we require substantial, additional funds through public or private equity or debt financings or other sources, such as strategic partnerships and alliances and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

Our future capital requirements depend on many factors, including:

- the number and characteristics of products we develop from our ApoGraft technology platform;
- the scope, progress, results and costs of researching and developing our ApoGraft technology platform and any future products, and conducting preclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- the cost of commercialization activities if any products are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing any future product we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing, supply or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs of in-licensing further patents and technologies;
- the cost of development of in-licensed technologies;
- the timing, receipt and amount of sales of, or royalties on, any future products;
- the expenses needed to attract and retain skilled personnel; and
- any product liability or other lawsuits related to any future products.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities for our ApoGraft technology platform or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our ApoGraft technology platform, our ApoTainer collection kits or any future products.

We will need additional capital in the future. Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We will require additional capital in the future. We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect shareholder rights and may cause the market price of our shares to decline. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or any products, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves.

Risks Related to Product Development and Regulatory Approval

Our product development program is based on a novel functional stem cell selection technology platform and is inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our ApoGraft technology platform creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third-party reimbursement, and market acceptance, which makes it difficult to predict the time and cost of any product development and subsequently obtaining regulatory approval. These challenges may prevent us from developing and commercializing products on a timely or profitable basis or at all.

Our ApoGraft technology platform is in an early stage of discovery and development, and we may fail to develop any commercially acceptable or profitable products.

We are concentrating our efforts on developing our first line of products, our ApoTainer collection kits, which is based on our ApoGraft technology platform, to improve the safety and efficacy of allogeneic HSCT. To date, we have only begun to conduct clinical trials. As such, we have yet to develop any products that have been approved for marketing, and our future success depends on the successful proof of concept of the ApoGraft technology platform and development of our ApoTainer selection kits for HSCT. There can be no assurance that any development problems we experience in the future related to our technology platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing the ApoGraft technology platform and our ApoTainer selection kits on a timely or profitable basis, if at all. Our ApoTainer selection kits are not expected to be commercially available for several years, if at all.

If the FDA classifies our ApoTainer selection kits as a drug, biologic or a combination product subject to the primary jurisdiction of the Center for Drug Evaluation and Research or Center for Biologics Evaluation and Research, we may not be able to obtain the necessary approval to market our ApoTainer selection kits or other products based on our ApoGraft technology platform in a timely manner or at all. Even if we do obtain approval, the cost and delay could materially adversely affect our financial condition, results of operations and cash flows.

We plan to bring our ApoTainer selection kits to market for HSCT as a medical device subject to the primary jurisdiction of Center for Biologics Evaluation and Research, or CBER. The classification of our ApoTainer selection kits by the FDA as a drug, a medical device or a combination product depends upon, among other things, the regulatory definition of a drug and a device, their primary mode of action and the indications for use or product claims. In February 2019, we filed a Pre-Request for Designation, or Pre-RFD to the FDA to designate the Apotainer as a medical device under the regulation of the CBER. Under the Pre-RFD, the FDA will provide a preliminary, nonbinding assessment of the regulatory identity or classification of our ApoTainer selection kits and an assessment of which Center will regulate the product. We also believe that due to its novelty and being first in class this product could be classified as a “de-novo” which could allow for less clinical data before marketing approval. However, if the FDA does not designate the ApoTainer as a medical device or later changes the regulatory identity or classification or if it is not classified as “de novo,” then we expect the approval process of our ApoTainer selection kits to be more burdensome and lengthy than if our ApoTainer selection kits were classified as a medical device. The cost and delay in the approval process could materially adversely affect our financial condition and results of operations and cash flows.

Future results released from our ongoing open-label Phase I/II clinical trial may differ materially from interim or pre-clinical trial results.

Clinical trials are inherently risky and may reveal that our ApoGraft platform technology is ineffective or has unanticipated interactions that may significantly decrease trial success. Our pre-clinical trial results and our interim results of our ongoing Phase I/II clinical trial of ApoGraft or any other interim results may differ materially from final results and do not necessarily predict favorable final results.

We may face numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent commercialization of our ApoGraft platform technology and ApoTainer selection kits or any future product. These clinical trials could be affected by negative or inconclusive trial results, unexpected delays, unanticipated patient drop-out rates or adverse side effects and future actions by regulatory authorities or additional expenses.

Clinical trials necessary to demonstrate proof of concept of the ApoGraft technology platform and support approval for our ApoTainer selection kits or any future products are expensive and could require the enrollment of large numbers of suitable patients, who could be difficult to identify and recruit. Delays or failures in any necessary clinical trials could prevent us from commercializing our ApoGraft technology platform and ApoTainer selection kits or any future product and could adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to demonstrate proof of concept of the ApoGraft technology platform and support approval for our ApoTainer selection kits or any future products that we may develop, or additional safety and efficacy data that the FDA may require for any new specific indications of our technology that we may seek, are time consuming and expensive with an uncertain outcome.

Conducting successful clinical trials could require the enrollment of large numbers of patients, and suitable patients could be difficult to identify and recruit. To date, we have experienced delays in our ongoing Phase I/II clinical study largely related to slower than expected recruitment. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, the proximity to clinical sites of patients that are able to comply with the eligibility and exclusion criteria for participation in the clinical trial, and patient compliance. For example, patients could be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to our product candidates.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy will be required and we may not adequately develop such protocols to support clearance or approval. Further, the FDA could require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial could cause an increase in costs and delays in the approval and attempted commercialization of our product candidates or result in the failure of the clinical trial. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

The results of our clinical trials may not support our product candidate claims or any additional claims we may seek for our products and our clinical trials may result in the discovery of adverse side effects.

Even if any clinical trial that we need to undertake is completed as planned, we cannot be certain that its results will support our product candidate claims or any new indications that we may seek for our products or that the FDA or foreign authorities will agree with our conclusions regarding the results of those trials. The clinical trial process may fail to demonstrate that our products or a product candidate is safe and effective for the proposed indicated use, which could cause us to stop seeking additional clearances or approvals for our ApoTainer selection kits, abandon our ApoGraft technology platform or delay development of other product candidates. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize a product candidate. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

We might be unable to develop product candidates that will achieve commercial success in a timely and cost-effective manner, or ever.

Even if regulatory authorities approve our ApoTainer selection kits or any other product we develop, they may not be commercially successful. Our ApoTainer selection kits or any other product we develop may not be commercially successful because government agencies and other third-party payors may not cover the product or the coverage may be too limited to be commercially successful; physicians, researchers and others may not use or recommend our products, even following regulatory approval. A product approval, assuming one issues, may limit the uses for which the product may be distributed thereby adversely affecting the commercial viability of the product. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. Third parties may develop superior products or have proprietary rights that preclude us from marketing our products. We also expect that at least some of our product candidates will be expensive, if approved. Demand for any ApoTainer selection kits or any other product we develop for which we obtain regulatory approval or license will depend largely on many factors, including but not limited to the extent, if any, of reimbursement of costs by government agencies and other third-party payors, pricing, the effectiveness of our marketing and distribution efforts, the safety and effectiveness of alternative products, and the prevalence and severity of side effects associated with our products. If physicians, government agencies and other third-party payors do not accept our products, we will not be able to generate significant revenue.

If we fail to obtain regulatory approval in jurisdictions outside the United States, we will not be able to market our products in those jurisdictions.

We intend to seek regulatory approval for our ApoTainer selection kits in a number of countries outside of the United States and expect that these countries will be important markets for our products, if approved. Marketing our products in these countries will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The regulations that apply to the conduct of clinical trials and approval procedures vary from country to country and may require additional testing. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any foreign market.

If we fail to obtain or maintain orphan exclusivity for our products we will have to rely on our data and marketing exclusivity, if any, and on our intellectual property rights, which may reduce the length of time that we can prevent competitors from selling generic versions of our products.

In September 2017, we announced that the FDA granted orphan drug designation for ApoGraft for the prevention of acute and chronic GvHD in transplant patients. 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, defined, in part, as a patient population of fewer than 200,000 in the U.S.

In the U.S., the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full New Drug Application, or NDA, to market the same drug for the same orphan indication, except in very limited circumstances. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later 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.

The EMA grants orphan drug designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the E.U. Orphan drug designation from the EMA provides ten years of marketing exclusivity following drug approval, subject to reduction to six years if the designation criteria are no longer met.

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 safer, more effective or makes a major contribution to patient care.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Although we believe that our ApoGraft technology platform has broad application, because we have limited financial and managerial resources, we are currently focused on development of our ApoTainer selection kits for HSCT in order to demonstrate commercial viability of our technology platform. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other 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 and product candidates for specific indications 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 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.

We will need to outsource and rely on third parties for the clinical development and manufacture, sales and marketing of our current product candidates or any future product candidates that we may develop, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.

We do not have the required financial and human resources to carry out on our own all the preclinical and clinical development for our ApoTainer selection kits or any other or future product candidates that we may develop, and do not have the capability and resources to manufacture, market or sell our ApoTainer selection kits or any future product candidates that we may develop. Our business model calls for the partial or full outsourcing of the clinical and other development and manufacturing, sales and marketing of our product candidates in order to reduce our capital and infrastructure costs as a means of potentially improving our financial position. Our success will depend on the performance of these outsourced providers. If such providers fail to perform adequately, our development of product candidates may be delayed and any delay in the development of our product candidates would have a material and adverse effect on our business prospects.

If we or our contractors or service providers fail to comply with regulatory laws and regulations, we or they could be subject to regulatory actions, which could affect our ability to develop, market and sell our product candidates and any other or future product candidates that we may develop and may harm our reputation.

If we or our manufacturers or other third-party contractors fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to regulatory actions, which could affect our ability to develop, market and sell our ApoTainer selection kits or any future product candidates under development successfully and could harm our reputation and lead to reduced demand for or non-acceptance of our proposed product candidates by the market. Even technical recommendations or evidence by the FDA through letters, site visits, and overall recommendations to academia or biotechnology companies may make the manufacturing of a product extremely labor intensive or expensive, making the product candidate no longer viable to manufacture in a cost efficient manner. The mode of administration may make the product candidate not commercially viable. The required testing of the product candidate may make that candidate no longer commercially viable. The conduct of clinical trials may be critiqued by the FDA, or a clinical trial site's Institutional Review Board or Institutional Biosafety Committee, which may delay or make impossible clinical testing of a product candidate. The Institutional Review Board for a clinical trial may stop a trial or deem a product candidate unsafe to continue testing. This may have a material adverse effect on the value of the product candidate and our business prospects.

Disruptions in our supply chain could delay any preclinical or clinical trials and the commercial launch of our product candidates.

Any significant disruption in our supplier relationships could harm our business. We currently rely on a single source supplier for the apoptotic inducing signal, Fas ligand, or FasL, that we use, and we may rely on a limited number of suppliers for other raw material we use. We have experienced delays in the supply of FasL for our planned second human ApoGraft trial and while we believe we have addressed these supply issues, there can be no assurance that we will not experience delays in supply of FasL in the future. If our current supplier or any other supplier suffers a major natural or man-made disaster at its manufacturing facility, or if they otherwise cease to supply to us, then this could result in further delays in our clinical studies and may delay product testing and potential regulatory approval until a qualified alternative supplier is identified. With respect to other raw materials for the ApoGraft technology platform, although alternative sources of supply exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers. If our manufacturers or we are unable to purchase any key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Should our products be approved for commercialization, adverse changes in reimbursement policies and procedures by payors may impact our ability to market and sell our products.

Healthcare costs have risen significantly over the past decade, and there have been and continue to be proposals by legislators, regulators and third-party payors to decrease costs. Third-party payors are increasingly challenging the prices charged for medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. For example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, PPACA, among other things, reduced and/or limited Medicare reimbursement to certain providers. The Budget Control Act of 2011, as amended by subsequent legislation, further reduces Medicare's payments to providers by 2% through fiscal year 2024. These reductions may reduce providers' revenues or profits, which could affect their ability to purchase new technologies. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Legislation could be adopted in the future that limits payments for our products from governmental payors. In addition, commercial payors, such as insurance companies, could adopt similar policies that limit reimbursement for medical device manufacturers' products. Therefore, we cannot be certain that our products or the procedures or patient care performed using our products will be reimbursed at a cost-effective level. We face similar risks relating to adverse changes in reimbursement procedures and policies in other countries where we may market our products. Reimbursement and healthcare payment systems vary significantly among international markets. Our inability to obtain international reimbursement approval, or any adverse changes in the reimbursement policies of foreign payors, could negatively affect our ability to sell our products and have a material adverse effect on our business and financial condition.

Should our products be approved for commercialization, our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

PPACA currently imposes, among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be \$38 billion over the next decade. The Internal Revenue Service issued final regulations implementing the tax in December 2012, which requires, among other things, bi-monthly payments and quarterly reporting. Once we market products, we will be subject to this or any future excise tax on our sales of certain medical devices in the United States. To the extent our products are considered medical devices, we anticipate that primarily all of our sales, once commenced, of medical devices in the United States will be subject to this 2.3% excise tax.

Public perception of ethical and social issues surrounding the use of stem cell technology may limit or discourage the use of our technologies.

For social, ethical, or other reasons, governmental authorities in the United States and other countries may call for limits on, or regulation of the use of, stem cell technologies. Although our platform technology is designed to enrich the stem cell population as an enabling technology rather than manufacture stem cells, claims that stem cell technologies are ineffective, unethical or pose a danger to the environment may influence public attitudes. The subject of stem cell technologies in general has received negative publicity and aroused public debate in the United States and some other countries. Ethical and other concerns about our stem cell technology could materially hurt the market acceptance of our technologies.

Our business and operations may be materially adversely affected in the event of computer system failures or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, fire, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, access to our clinical data, or disruption of the manufacturing process, we could incur liability and the further development of our drug candidates could be delayed. We may also be vulnerable to cyber-attacks by hackers or other malfeasance. This type of breach of our cybersecurity may compromise our confidential information and/or our financial information and adversely affect our business or result in legal proceedings. Further, these cybersecurity breaches may inflict reputational harm upon us that may result in decreased market value and erode public trust.

The members of our management team and certain consultants are important to the efficient and effective operation of our business. Failure to retain our management and consulting team could have a material adverse effect on our business, financial condition or results of operations.

Our senior management and technical personnel, as well as certain consultants, are important to the efficient and effective operation of our business, particularly Dr. Shai Yarkoni, our Chief Executive Officer. Our failure to retain the personnel that have developed much of the technology we utilize today, or any other key management and technical personnel, could have a material adverse effect on our future operations. Our success is also dependent on our ability to attract, retain and motivate highly trained technical and management personnel, among others, to continue the development and commercialization of our current and future products. As of the date of this update, we do not have key-man insurance on any of our officers or consultants.

As such, our future success highly depends on our ability to attract, retain and motivate personnel, including contractors, required for the development, maintenance and expansion of our activities. There can be no assurance that we will be able to retain our existing personnel or attract additional qualified employees or consultants. The loss of personnel or the inability to hire and retain additional qualified personnel in the future could have a material adverse effect on our business, financial condition and results of operation.

We face significant competition. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may never be profitable.

The field of regenerative medicine is expanding rapidly, mainly in uses of stem cells but also in the development of cell-based therapies and/or devices designed to isolate stem and progenitor cells from human tissues. As the field grows, we face, and will continue to face, increased competition from pharmaceutical, biopharmaceutical, medical device and biotechnology companies, as well as academic and research institutions and governmental agencies in the United States and abroad. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs than we do, and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing stem cell selection technology;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA approvals and addressing various regulatory matters and obtaining other regulatory approvals;
- manufacturing medical devices; and
- launching, marketing and selling medical devices.

We are aware of two companies that lead the stem cell selection market with whom we directly compete. The first is Miltenyi Biotec, or Miltenyi, which dominates the stem cell selection market, using biomarkers to either enrich stem cells (positive selection by CD34) or deplete mature hematopoietic cells such as T cells from the biological sample (negative selection by monoclonal activity against T-cell receptor), resulting in the enrichment of stem and progenitor cells. The second is Cytori Therapeutics, or Cytori, which sells a medical device known as the Celution® System that enables bedside access to adult adipose-derived stem and regenerative cells, or ADRCs, by automating and standardizing the extraction, washing, and concentration of a patient's own ADRCs for present and future clinical use. We believe that both technologies result in less than optimal cell population both in terms of quantity and quality (purity) of the selected population of cells.

In addition, since we are developing our ApoTainer selection kits to improve the safety and efficacy of allogeneic HSCT, we also compete with companies developing treatments for GvHD, a life-threatening condition associated with allogeneic HSCT.

In the general area of cell-based therapies, we may now or in the future compete on an indirect basis with a variety of companies, most of whom are specialty medical products or biotechnology companies that provide a finished stem cell product that has already undergone stem cell selection. We believe, however, that many of these companies have the potential to become customers in the future of our ApoGraft technology platform in order to improve and enhance their in-house processes.

If our competitors develop and commercialize products faster than we do, or develop and commercialize products that are superior to our ApoGraft technology platform or ApoTainer selection kits, our commercial opportunities will be reduced or eliminated. Our competitors may succeed in developing and commercializing products earlier and obtaining regulatory approvals from the FDA and foreign regulatory authorities more rapidly than we do. Our competitors may also develop products or technologies that are superior to those we are developing, and render our product candidate obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may never be profitable.

The extent to which our product candidate achieves market acceptance will depend on competitive factors, many of which are beyond our control. Competition in the field of regenerative medicine is intense and has been accentuated by the rapid pace of technology development. Our competitors also compete with us to:

- attract parties for acquisitions, joint ventures or other collaboration;
- license proprietary technology that is competitive with ApoGraft technology platform or ApoTainer selection kits;
- attract funding; and
- attract and hire scientific talent and other qualified personnel.

Product liability and other claims against us may in the future reduce demand for our products or result in substantial damages. We anticipate that we will need to obtain and maintain additional or increased insurance coverage, and we may not be able to obtain or maintain such coverage on commercially reasonable terms, if at all.

A product liability claim, a clinical trial liability claim or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business. Our business exposes us to potential liability risks that may arise from any future clinical testing of our product candidates in human clinical trials and the manufacture and sale of any approved products. Any clinical trial liability or product liability claim or series of claims or class actions brought against us, with or without merit, could result in:

- liabilities that substantially exceed any clinical trial liability or product liability insurance that we may obtain in the future, which we would then be required to pay from other sources, if available;
- an increase in the premiums we may pay for any clinical trial liability or product liability insurance we may obtain in the future or the inability to renew or obtain clinical trial liability or product liability insurance coverage in the future on acceptable terms, or at all;
- withdrawal of clinical trial volunteers or patients;
- damage to our reputation and the reputation of our products, including loss of any future market share;
- regulatory investigations that could require costly recalls or product modifications;
- litigation costs; and
- diversion of management's attention from managing our business.

We do not currently have product liability insurance because none of our product candidates has yet been approved for commercialization. If any of our product candidates are sold commercially, we will seek product liability insurance coverage. We cannot assure you that we will be able to maintain clinical trial or obtain and product liability insurance on commercially acceptable terms, if at all, or that we will be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect against potential losses.

If our employees commit fraud or other misconduct, including noncompliance with regulatory standards and requirements and insider trading, our business may experience serious adverse consequences.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to report financial information or data accurately or to 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, 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. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

Our board of directors has adopted a Code of Ethics which became effective upon the listing of our ADSs on Nasdaq. However, 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 be in compliance with such 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.

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and the market price of the ADSs. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

We may encounter difficulties in managing our growth. Failure to manage our growth effectively will have a material adverse effect on our business, results of operations and financial condition.

We may not be able to successfully grow and expand. Successful implementation of our business plan will require management of growth, including potentially rapid and substantial growth, which will result in an increase in the level of responsibility for management personnel and place a strain on our human and capital resources. To manage growth effectively, we will be required to continue to implement and improve our operating and financial systems and controls to expand, train and manage our employee base. Our ability to manage our operations and growth effectively will require us to continue to expend funds to enhance our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient talented personnel. If we are unable to scale up and implement improvements to our control systems in an efficient or timely manner, or if we encounter deficiencies in existing systems and controls, then we will not be able to successfully commercialize our ApoGraft technology platform, our ApoTainer selection kits or any future product candidate. Failure to attract and retain sufficient talented personnel will further strain our human resources and could impede our growth or result in ineffective growth. Moreover, the management, systems and controls currently in place or to be implemented may not be adequate for such growth, and the steps we have taken to hire personnel and to improve such systems and controls might not be sufficient. If we are unable to manage our growth effectively, it will have a material adverse effect on our business, results of operations and financial condition.

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

Our business will expose us to potential liability that results from risks associated with conducting any future clinical trials of our ApoTainer selection kits or any future product candidate. A successful clinical trial liability claim, if any, brought against us could have a material adverse effect on our business, prospects, financial condition and results of operations even though clinical trial insurance is successfully maintained or obtained. Our planned insurance coverage may only mitigate a small portion of a substantial claim against us. In addition, we may be unable to maintain sufficient insurance as a public company to cover liability claims made against our officers and directors. If we are unable to adequately insure our officers and directors, we may not be able to retain or recruit qualified officers and directors to manage us.

Recent disruptions in the financial markets and economic conditions could affect our ability to raise capital.

In recent years, the United States and global economies suffered dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. The United States and certain foreign governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If the actions taken by these governments are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

Our current management team has limited experience in managing and operating a publicly traded U.S. company. Any failure to comply or adequately comply with federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, results of operations and financial condition.

Our current management team has a limited experience managing and operating a publicly traded U.S. company. Failure to comply or adequately comply with any laws, rules or regulations applicable to our business may result in fines or regulatory actions, which may materially adversely affect our business, results of operation or financial condition, and could result in delays in achieving the development of an active and liquid trading market for the ADSs.

Risks Related to Our Intellectual Property

We rely upon patents to protect our technology.

The patent position of biotechnology firms is generally uncertain and involves complex legal and factual questions. We do not know whether any of our current or future patent applications will result in the issuance of any patents. Even issued patents may be challenged, invalidated or circumvented. Patents may not provide a competitive advantage or afford protection against competitors with similar technology. Competitors or potential competitors may have filed applications for, or may have received patents and may obtain additional and proprietary rights to compounds or processes used by or competitive with ours.

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 noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. Patent and Trademark Office (USPTO) and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to office actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and ultimately unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or 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 proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect us.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our platform technology without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the medical device and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology or use of our technology does not infringe third-party patents. It is also possible that we have failed to identify relevant third-party patents or applications that may have been issued or pending in the US or in a foreign jurisdiction. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest date which they are entitled to, which is referred to as the priority date. Therefore, it cannot be ruled out that patent applications covering our technology were filed by others in the last 18 months about which we cannot have any knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our technology.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our technology, including inter parties review, interference, or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our technology or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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 and Israel can be less extensive than those in the United States and Israel. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as laws in the United States and Israel. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States and Israel, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and further, may export otherwise infringing products to territories where we have patents, but enforcement is not as strong as that in the United States and Israel.

Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain other developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to medical devices and biopharmaceutical 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. To date, we have not sought to enforce any issued patents in these foreign jurisdictions. 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. The requirements for patentability may differ in certain countries, particularly developing countries. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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.

We rely on confidentiality agreements that could be breached and may be difficult to enforce, which could result in third parties using our intellectual property to compete against us.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to enter into these types of agreements with our contractors, consultants, advisors and research collaborators, to the extent that employees and consultants utilize or independently develop intellectual property in connection with any of our projects, disputes may arise as to the intellectual property rights associated with our Powered by Collect technology platform, our ApoTainer selection kits or any future product candidate. If a dispute arises, a court may determine that the right belongs to a third party. In addition, enforcement of our rights can be costly and unpredictable. We also rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;

- these agreements may not provide adequate remedies for the applicable type of breach;
- our proprietary know-how will otherwise become known; or
- our competitors will independently develop similar technology or proprietary information.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to develop technology that is similar to our Powered by Celect technology platform, our ApoTainer selection kits or any future product candidate, but that is not covered by the claims of the patents that we own;
- we or any future strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise 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. 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. In addition, the Israeli Supreme Court ruled in 2012 that an employee who receives a patent or contributes to an invention during his employment may be allowed to seek compensation for such contributions from his or her employer, even if the employee's contract of employment specifically states otherwise and the employee has transferred all intellectual property rights to the employer. The Israeli Supreme Court ruled that the fact that a contract revokes an employee's right for royalties and compensation does not rule out the right of the employee to claim their right for royalties. As a result, it is unclear whether and, if so, to what extent our employees may be able to claim compensation with respect to our future revenue. We may receive less revenue from future products if any of our employees successfully claim for compensation for their work in developing our intellectual property, which in turn could impact our future profitability.

Risks Related to Our Operations in Israel

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

Our head executive office, our research and development facilities, as well as some of our planned clinical sites, are or will be located in Israel. All our officers and a majority of our directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business and operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. During the summer of 2006 and the fall of 2012, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party. In December 2008, January 2009, November 2012 and July 2014, there were escalations in violence between Israel, on the one hand, and Hamas, the Palestinian Authority and/or other groups, on the other hand, as well as extensive hostilities along Israel's border with the Gaza Strip, which resulted in missiles being fired from the Gaza Strip into Southern and central Israel, including near Tel Aviv and at areas surrounding Jerusalem. These conflicts involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel. Our offices and laboratory, located in Kfar Saba, Israel, are within the range of the missiles and rockets that have been fired at Israeli cities and towns from Gaza sporadically since 2006, with escalations in violence (such as the recent escalation in July 2014) during which there were a substantially larger number of rocket and missile attacks aimed at Israel. In addition, since February 2011, Egypt has experienced political turbulence and an increase in terrorist activity in the Sinai Peninsula following the resignation of Hosni Mubarak as president. This turbulence included protests throughout Egypt, and the appointment of a military regime in his stead, followed by the elections to parliament which brought groups affiliated with the Muslim Brotherhood (which had been previously outlawed by Egypt), and the subsequent overthrow of this elected government by a military regime. Such political turbulence and violence may damage peaceful and diplomatic relations between Israel and Egypt, and could affect the region as a whole. Similar civil unrest and political turbulence has occurred in other countries in the region, including Syria, which shares a common border with Israel, and is affecting the political stability of those countries. Since April 2011, internal conflict in Syria has escalated, and evidence indicates that chemical weapons have been used in the region. This instability and any outside intervention may lead to deterioration of the political and economic relationships that exist between the State of Israel and some of these countries, and may have the potential for causing additional conflicts in the region. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and various rebel militia groups in Syria. Additionally, a violent jihadist group named Islamic State of Iraq and Levant (ISIL) is involved in hostilities in Iraq and Syria and have been growing in influence. Although ISIL's activities have not directly affected the political and economic conditions in Israel, ISIL's stated purpose is to take control of the Middle East, including Israel. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

Shareholders may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws, against us or our executive officers and directors, or asserting U.S. securities laws claims in Israel.

All our officers and a majority of our directors are residents of Israel. Most of our directors' and officers' assets and our assets are located outside the United States. Service of process upon us or our non-U.S. resident directors and officers and enforcement of judgments obtained in the United States against us or our non-U.S. directors and executive officers may be difficult to obtain within the United States. We have been informed by our legal counsel in Israel that it may be difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be 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. Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or our officers and directors.

Moreover, among other reasons, including but not limited to fraud or absence of due process, or the existence of a judgment which is at variance with another judgment that was given in the same matter if a suit in the same matter between the same parties was pending before a court or tribunal in Israel, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel.

Under applicable U.S. and Israeli law, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. In addition, employees may be entitled to seek compensation for their inventions irrespective of their agreements with us, which in turn could impact our future profitability.

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

In addition, Chapter 8 to the Israeli Patents Law, 5727-1967, or the Patents Law, deals with inventions made in the course of an employee's service and during his or her term of employment, whether or not the invention is patentable, or service inventions. Section 134 of the Patents Law sets forth that if there is no agreement which explicitly determines whether the employee is entitled to compensation for the service inventions and the extent and terms of such compensation, such determination will be made by the Compensation and Rewards Committee, a statutory committee of the Israeli Patents Office. The Israeli Supreme Court ruled in 2012 that an employee who contributes to a service invention during his or her employment may be allowed to seek compensation for such contributions from his employer, even if the employee's contract of employment specifically states otherwise and the employee has assigned all intellectual property rights to the employer. The Israeli Supreme Court ruled that the fact that a contract revokes the employee's right for royalties and compensation in connection with service inventions does not rule out the right of the employee to claim a right for royalties. Following such ruling, the Israeli Supreme Court remanded the proceedings to the District Court for further discussion and therefore the ultimate outcome has yet to be resolved. As a result, it is unclear if, and to what extent, our research and development employees may be able to claim compensation with respect to our future revenue. As a result, we may receive less revenue from future products if such claims are successful, which in turn could impact our future profitability.

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 respects from the rights and responsibilities of shareholders of U.S.-based corporations. In particular, a shareholder of an Israeli company, such as us, has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards us and other shareholders and to refrain from abusing its power in us, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to our articles of association, an increase of our authorized share capital, a merger 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 shareholders vote or to appoint or prevent the appointment of an office holder of ours or other power towards us has a duty to act in fairness towards us. However, Israeli law does not define the substance of this duty of fairness. Since Israeli corporate law underwent extensive revisions approximately 15 years ago, the parameters and implications of the provisions that govern shareholder behavior have not been clearly determined. 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.

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

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, the holder of a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives at least 95% of the issued share capital (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer, except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights).

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

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

Because a certain portion of our expenses is incurred in currencies other than the U.S. dollar, our results of operations may be harmed by currency fluctuations and inflation.

Our reporting and functional currency is the NIS, but some portion of our clinical trials and operations expenses are in the U.S. dollar and Euro. As a result, we are exposed to some currency fluctuation risks. For example, if the NIS strengthens against either the U.S. dollar or the Euro, our reported revenues in NIS may be lower than anticipated. The Israeli rate of inflation has not offset or compounded the effects caused by fluctuations between the NIS and the U.S. dollar or the Euro. To date, we have not engaged in hedging transactions. Although the Israeli rate of inflation has not had a material adverse effect on our financial condition during 2016, 2017, or 2018 to date, we may, in the future, decide to enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the currencies mentioned above in relation to the NIS. These measures, however, may not adequately protect us from adverse effects.

Because a certain portion of our expenses is incurred in currencies other than the U.S. dollar, our results of operations may be harmed by currency fluctuations and inflation.

Our reporting and functional currency is the NIS, but some portion of our clinical trials and operations expenses are in the U.S. dollar and Euro. As a result, we are exposed to some currency fluctuation risks.

Our operations may be disrupted as a result of the obligation of Israeli citizens to perform military service.

Many Israeli citizens are obligated to perform several days, and in some cases more, of annual military reserve duty each year until they reach the age of 40 (or older, for reservists who are military officers or who have certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by such call-ups, which may include the call-up of members of our management. Such disruption could materially adversely affect our business, financial condition and results of operations.

Risks Related to Ownership of Our ADSs or Warrants

We may not be able to raise additional funds unless we increase our authorized share capital.

As of March 12, 2019, we have 500,000,000 authorized ordinary shares, out of which 224,087,799 ordinary shares are outstanding (which excludes 2,641,693, shares held in treasury), 145,471,922 are reserved for future issuance under outstanding options and warrants and under our 2014 Collect Option Plan. Any equity financing necessary in order to fund our operations may require us to increase our authorized share capital prior to initiating any such financing transaction. Increasing our share capital is subject to the approval of our shareholders. In the event we fail to obtain the approval of our shareholders to such increase in our authorized share capital, our ability to raise sufficient funds, if at all, might be adversely effected.

We do not know whether a market for our securities will be sustained or what the trading price of our securities will be and as a result it may be difficult for you to sell our securities held by you.

Although our ADSs and listed warrants now trade on Nasdaq, an active trading market for the ADSs or listed warrants may not be sustained. It may be difficult for you to sell your ADSs, Pre-funded Warrants or Warrants without depressing the market price for the ADSs or listed warrants. As a result of these and other factors, you may not be able to sell your ADSs, Pre-funded Warrants or Warrants. Further, an inactive market may also impair our ability to raise capital by issuing securities and may impair our ability to enter into strategic partnerships or acquire companies or products by using our equity as consideration.

If we were to be characterized as a “passive foreign investment company” for U.S. tax purposes, U.S. holders of our ordinary shares, ADSs or warrants could have adverse U.S. income tax consequences.

If we were to be characterized as a passive foreign investment company, or PFIC, under the U.S. Internal Revenue Code of 1986, as amended, or the Code, in any taxable year during which a U.S. Holder (as defined below) owns ordinary shares, ADSs, or warrants, such U.S. Holder could be liable for additional taxes and interest charges upon certain distributions by us and any gain recognized on a sale, exchange or other disposition, including a pledge, of our ordinary shares, ADSs, or warrants whether or not we continue to be a PFIC. We believe that we were a PFIC for our 2018 taxable year. Because the PFIC determination is highly fact intensive, there can be no assurance that we will not be a PFIC for 2019 or for any other taxable year. U.S. Holders who hold ordinary shares, ADSs, or warrants during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC, subject to specified exceptions for U.S. Holders who made a “qualified electing fund” or “mark-to-market” election with respect to our ordinary shares or ADSs. A U.S. Holder may be able to mitigate some of the adverse U.S. federal income tax consequences with respect to owning ordinary shares or ADSs provided that such U.S. Holder is eligible to make, and successfully makes, a “mark-to-market” election. U.S. Holders of our ordinary shares or ADSs could also mitigate some of the adverse U.S. federal income tax consequences of us being classified as a PFIC by making a “qualified electing fund” election. Such elections would be unavailable with respect to our warrants. Upon request, we expect to provide the information necessary for U.S. Holders to make “qualified electing fund” elections if we are classified as a PFIC. U.S. Holders are strongly urged to consult their tax advisors about the PFIC rules, including tax return filing requirements and the eligibility, manner, and consequences to them of making a “qualified electing fund” or “mark-to-market” election with respect to our ordinary shares, ADSs, and warrants in the event that we qualify as a PFIC.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of the ADSs.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. We will be required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal control, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. Disclosing deficiencies or weaknesses in our internal control, failing to remediate these deficiencies or weaknesses in a timely fashion or failing to achieve and maintain an effective internal control environment may cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of the ADSs. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed.

As an “emerging growth company” under the JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements, which could make the ADSs or warrants less attractive to investors.

For as long as we are deemed an emerging growth company, we are permitted to and intend to take advantage of specified reduced reporting and other regulatory requirements that are generally unavailable to other public companies, including:

- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting required by Section 404 of the Sarbanes-Oxley Act; and
- an exemption from compliance with any new requirements adopted by the PCAOB, requiring mandatory audit firm rotation or a supplement to the auditor’s report in which the auditor would be required to provide additional information about our audit and our financial statements.

We will be an emerging growth company until the earliest of: (i) the last day of the fiscal year during which we had total annual gross revenues of \$1.07 billion or more, (ii) the last day of the fiscal year following the fifth anniversary of the date of the first sale of the ADSs pursuant to an effective registration statement, (iii) the date on which we have, during the previous three-year period, issued more than \$1 billion in non-convertible debt or (iv) the date on which we are deemed a “large accelerated filer” as defined in Regulation S-K under the Securities Act of 1933, as amended (the “Securities Act”).

We cannot predict if investors will find the ADSs or warrants less attractive because we may rely on these exemptions. If some investors find the ADSs or warrants less attractive as a result, there may be a less active trading market for the ADSs or warrants and the market price of the ADSs may be more volatile.

We are a “foreign private issuer” and have disclosure obligations that are different from those of U.S. domestic reporting companies.

We are a foreign private issuer and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the Securities and Exchange Commission (the “SEC”). Under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), we will be subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we will not be required to issue quarterly reports or proxy statements that comply with the requirements applicable to U.S. domestic reporting companies. Furthermore, although under a recent amendment to the regulations promulgated under the Israeli Companies Law, as amended, or the Companies Law, as an Israeli public company listed overseas we will be required to disclose the compensation of our five most highly compensated officers on an individual basis (rather than on an aggregate basis, as was previously permitted for Israeli public companies listed overseas prior to such amendment), this disclosure will not be as extensive as that required of U.S. domestic reporting companies. We will also have four months after the end of each fiscal year to file our annual reports with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our officers, directors and principal shareholders will be exempt from the requirements to report transactions and short-swing profit recovery required by Section 16 of the Exchange Act. Also, as a “foreign private issuer,” we are not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. These exemptions and leniencies will reduce the frequency and scope of information and protections available to you in comparison to those applicable to a U.S. domestic reporting companies.

As a “foreign private issuer,” we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers.

As a “foreign private issuer,” we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the listing rules of Nasdaq for domestic U.S. issuers. For instance, we follow home country practice in Israel with regard to, among other things, board of directors independence requirements, director nomination procedures, compensation committee matters. In addition, we will follow our home country law instead of the listing rules of Nasdaq that require that we obtain shareholder approval for certain dilutive events, such as the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of us, certain transactions other than a public offering involving issuances of a 20% or greater interest in the company, and certain acquisitions of the stock or assets of another company. We may in the future elect to follow home country corporate governance practices in Israel with regard to other matters. Following our home country corporate governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on Nasdaq may provide less protection to you than what is accorded to investors under the listing rules of Nasdaq applicable to domestic U.S. issuers.

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

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

The market price for our ADSs and listed warrants may be volatile.

The market price for our ADSs and listed warrants is likely to be highly volatile and subject to wide fluctuations in response to numerous factors including the following:

- our failure to obtain the approvals necessary to commence clinical trials;
- results of clinical and preclinical studies;
- announcements of regulatory approval or the failure to obtain it, or changes or delays in the regulatory review process;
- announcements of technological innovations, new products or product enhancements by us or others;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws, regulations or decisions applicable to our product candidates or patents;
- any adverse changes to our relationship with manufacturers or suppliers;

- announcements concerning our competitors or the regenerative medicine or healthcare industries in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of or results of, or involvement in, litigation, including, but not limited to, any product liability actions or intellectual property infringement actions;
- any major changes in our board of directors, management or other key personnel;
- announcements by us of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments;
- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of our products that we, our licensees or others develop;
- success of research and development projects;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares or the ADSs or the warrants are covered by analysts;
- future issuances of ordinary shares, ADSs or warrants or other securities;
- general market conditions, including the volatility of market prices for shares of healthcare companies generally, and other factors, including factors unrelated to our operating performance; and
- the other factors described in this "Risk Factors" section.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of the ADSs and warrants, which would result in substantial losses by our investors. In addition, the securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of any particular company. These market fluctuations may also have a material adverse effect on the market price of the ADSs and warrants.

Substantial future sales or perceived potential sales of our ordinary shares or ADSs or listed warrants in the public market could cause the price of our ADSs or listed warrants to decline.

Substantial sales of our ADSs or listed warrants on Nasdaq may cause the market price of our ADSs and listed warrants to decline. Sales by us or our security holders of substantial amounts of our ADSs or listed warrants or the perception that these sales may occur in the future, could cause a reduction in the market price of our shares ADSs or listed warrants. The issuance of any additional ordinary shares or any additional ADSs or warrants, or any securities that are exercisable for or convertible into our ordinary shares or ADSs, may have an adverse effect on the market price of our ADSs or listed warrants and will have a dilutive effect on our existing shareholders and holders of ADSs or warrants.

We have not paid, and do not intend to pay, dividends on our ordinary shares and, therefore, unless our traded securities appreciate in value, our investors may not benefit from holding our securities.

We have not paid any cash dividends on our ordinary shares since inception. We do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. Moreover, the Companies Law imposes certain restrictions on our ability to declare and pay dividends. As a result, investors in our ADSs or ordinary shares, or investors who exercise our warrants, will not be able to benefit from owning these securities unless their market price becomes greater than the price paid by such investors and they are able to sell such securities. We cannot assure you that you will ever be able to resell our securities at a price in excess of the price paid.

You may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive dividends or other distributions on our ordinary shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.

The depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. You will receive these distributions, if any, in proportion to the number of ordinary shares your ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act, but that are not properly registered or distributed under an applicable exemption from registration. In addition, conversion into U.S. dollars from foreign currency that was part of a dividend made in respect of deposited ordinary shares may require the approval or license of, or a filing with, any government or agency thereof, which may be unobtainable. In these cases, the depositary may determine not to distribute such property and hold it as “deposited securities” or may seek to effect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation to register under U.S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. In addition, the depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that you may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

Holders of ADSs must act through the depositary to exercise their rights as our shareholders.

Holders of the ADSs do not have the same rights of our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law, the minimum notice period required to convene a shareholders meeting is no less than 35 or 21 calendar days, depending on the proposals on the agenda for the shareholders meeting. When a shareholder meeting is convened, holders of the ADSs may not receive sufficient notice of a shareholders meeting to permit them to withdraw their ordinary shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of the ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of the ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ADSs. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of the ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested. In addition, in the capacity as a holder of ADSs, they will not be able to call a shareholders meeting.

You may be subject to limitations on transfer of your ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement.

Your percentage ownership in us may be diluted by future issuances of share capital, which could reduce your influence over matters on which shareholders vote.

Our board of directors has the authority, in most cases without action or vote of our shareholders, to issue all or any part of our authorized but unissued shares, including ordinary shares issuable upon the exercise of outstanding warrants and options. Issuances of additional shares would reduce your influence over matters on which our shareholders vote.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal and commercial name is Collect Biotechnology Ltd. We were established as a private company limited by shares under the laws of the State of Israel on August 4, 1986, under the name Montiger Ltd. Between 1986 and 2013, we underwent several name changes, most recently on August 28, 2013, when we changed our name from T.R.F. Capital Ltd. to Collect Biomed Ltd. On May 16, 2016, we obtained shareholder approval to change our name to Collect Biotechnology Ltd. We formally changed our name to Collect Biotechnology Ltd. on July 21, 2016. On July 29, 2016, our ADSs and warrants, commenced trading on the Nasdaq Capital Market under the symbols “APOP” and “APOPW”, respectively. From 1990 to September 3, 2017, our shares were traded on the TASE.

From October 25, 2012 until July 1, 2013, we did not have any business operations, excluding administrative management. On June 30, 2013, a general meeting of our shareholders approved our merger by way of share exchange with Collect Biotherapeutics Ltd., or Collect Biotherapeutics. As a result of the merger, which closed on July 1, 2013, Collect Biotherapeutics became a wholly owned subsidiary and we issued to shareholders of Collect Biotherapeutics 44,887,373 ordinary shares, options (Series 1) exercisable for 227,358 ordinary shares, and options (Series 2) exercisable for 341,037 ordinary shares (all of such 341,037 options were subsequently exercised into ordinary shares), which constituted approximately 85% of our then outstanding share capital and 85% of our then outstanding share capital on a fully diluted basis.

Collect Biotherapeutics was established as a private company limited by shares under the State of Israel on June 9, 2011 for the purpose of developing novel and unique technologies that allow the functional selection of stem cells through the substantial reduction of the complications that exist today in acceptable selection methods and increasing the chances of success of stem cell therapies.

Our principal offices are located at 23 HaTa'as St., Kfar Saba, Israel 44425, and our telephone number is +972-9-974-1444. Our primary internet address is www.collect.co. None of the information on our website is incorporated by reference herein. Puglisi & Associates, or Puglisi, serves as our authorized representative in the United States for certain limited matters. Puglisi's address is 850 Library Avenue, Newark, Delaware 19711.

We use our website (<http://www.collect.co>) as a channel of distribution of Company information. The information we post through this channel may be deemed material. Accordingly, investors should monitor these channels, in addition to following our press releases, SEC filings and public conference calls and webcasts. The contents of our website and social media channels are not, however, a part of this annual report.

We are an emerging growth company, as defined in Section 2(a) of the Securities Act, as implemented under the JOBS Act. As such, we are eligible to, and intend to, take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies including but not limited to not being required to comply with the auditor attestation requirements of the SEC rules under Section 404 of the Sarbanes-Oxley Act. We will be an emerging growth company until the earliest of: (i) the last day of the fiscal year during which we had total annual gross revenues of \$1.07 billion or more, (ii) the last day of the fiscal year following the fifth anniversary of the date of the first sale of the ADSs pursuant to an effective registration statement (i.e. December 31, 2021), (iii) the date on which we have, during the previous three-year period, issued more than \$1 billion in non-convertible debt or (iv) the date on which we are deemed a "large accelerated filer" as defined in Regulation S-K under the Securities Act, which means the market value of our ordinary shares that is held by non-affiliates exceeds \$700 million as of the prior June 30th.

We are a foreign private issuer as defined by the rules under the Securities Act and the Exchange Act. Our status as a foreign private issuer also exempts us from compliance with certain laws and regulations of the SEC and certain regulations of the Nasdaq Capital Market, including the proxy rules, the short-swing profits recapture rules, and certain governance requirements such as independent director oversight of the nomination of directors and executive compensation. In addition, we will not be required to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies registered under the Exchange Act.

Our capital expenditures for December 31, 2018, 2017 and 2016 amounted to NIS 0.7 million (approximately \$0.2 million), NIS 0.3 million (approximately \$0.09 million), and NIS 0.6 million (approximately \$0.15 million). Our purchases of fixed assets primarily include laboratory equipment used for the development of our clinical treatment. We financed these expenditures primarily from cash on hand.

B. Business Overview

We are an emerging biotechnology company that has developed a novel technology platform known as ApoGraft that functionally selects stem cells in order to improve the safety and efficacy of regenerative medicine and cell therapies. We aim to become the standard enabling technology for the enrichment of the stem cell population for companies developing stem cell therapies, for physicians practicing regenerative medicine and for researchers and academia engaged in cell based medicine and research.

We believe our innovative technology platform represents a potential breakthrough in the field of regenerative medicine by using functional selection of stem cells. Efficient selection enables retention of most of the stem cells from various starting bulk of cells while neutralizing harmful mature cells from this bulk of raw material. Animal models suggest that this process results in dramatic decrease of toxicity coupled with the enrichment of the stem cell population.

Our ApoGraft technology platform takes advantage of a functional characteristic of stem cells relating to apoptosis. Apoptosis is the process of programmed cell death and is a vital part of physiological development and homeostasis of all organisms. Stem cells flourish in an environment where normal cells die because their major role is reconstitution of damaged tissue. Stem cells are attracted to areas of cell death, areas typified by very high levels of apoptotic activity and apoptotic-inducing signals.

We are currently developing our first product based on our ApoGraft technology platform, the ApoTainer selection kit that utilizes FasL-coated paramagnetic beads. The ApoTainer selection kit is intended to be an easy to use, cost effective, off the shelf stem cell selection kit. In October 2018, we announced that we optimized the beads size, coating technology, elimination of the release of FasL into the medium, all while preserving the biological activity observed in our ongoing human clinical trial. Pre-clinical proof of concept testing of the ApoTainer has shown that the use of FasL-coated paramagnetic beads significantly increases the active surface allowing a dramatic increase of interactions between the selecting agent and the cells. Further, such testing showed that the outcome increases specific elimination of certain (but not all) of the non-stem cells while full preservation of the number and function of the stem and progenitor cells.

The ApoGraft technology platform is being tested for clinical use in allogeneic (using stem cells from a donor) hematopoietic stem cell transplantation, or HSCT for the treatment of hematological malignancies (blood cancers such as leukemia and lymphoma). HSCT, also known as bone marrow transplantation, has for decades been curative for many patients with hematological malignancies. Clinical trials have shown that HSCT can also be used for other non-malignant indications (such as autoimmune diseases) but is rarely used due to severe toxicity. Application of allogeneic HSCT is limited by graft-versus-host-disease, or GvHD, a condition in which the transplanted immune cells (populating the graft in much higher numbers than the stem cells) recognize the host cells and organs as foreign and attack them. GvHD does not resolve by itself and is a major cause of transplant-related morbidity and mortality. Despite improvements in the outcome of HSCT over recent years through improved supportive care, infection control and use of reduced intensity and reduced toxicity conditioning regimens, HSCT is still associated with significant morbidity and mortality mainly due to GvHD, and as such HSCT is restricted to patients with life threatening advanced diseases. Due to non-efficient selection of stem cells for HSCT, the complex and expansive laboratory process performed using technologies currently available is able to reduce toxicity only at a significant tradeoff — failure of engraftment, graft rejection, cancer reoccurrence and high costs of treatment.

We have chosen allogeneic HSCT for the treatment of hematological malignancies as our first target indication for our ApoGraft technology platform in order to clinically validate that our technology can efficiently select stem cells resulting in neutralizing harmful cells and their associated medical complications. We believe that demonstrating the safety of our technology for this indication will validate the use of our ApoGraft technology platform for the treatment of other indications (e.g., nonmalignant bone marrow failure, solid organ transplantation and auto-immune diseases) and consequently for the adoption of our ApoGraft technology platform by stem cell therapeutic companies, academia, researchers and others seeking to enrich their stem cell population. In that regard, we believe that after the first reported results of our human trials, as discussed further below, we will achieve validation of our product's safety profile, which may result in expediting further development of our technology for multiple indications before marketing approval is obtained. In addition, we believe such validation of our proof of concept will provide us with the opportunity to license our ApoGraft technology platform in the near term.

We currently plan to bring our ApoTainer selection kits to market for HSCT as a medical device and regulated under Center for Biologics Evaluation and Research, or CBER. In February 2019, we filed a Pre-Request for Designation, or Pre-RFD to the FDA to designate the Apotainer as a medical device under the regulation of the CBER. Under the Pre-RFD, the FDA will provide a preliminary, nonbinding assessment of the regulatory identity or classification of our ApoTainer selection kits and an assessment of which Center will regulate the product.

In September 2017, we announced that the FDA granted orphan drug designation for ApoGraft for the prevention of acute and chronic GvHD in transplant patients. We plan in the future to apply for fast track and breakthrough technology, which, if received, would result in a reduced cost of development and expedited marketing approvals, however there is no assurance that such designations will ever be obtained.

Our development efforts to date have primarily culminated in two studies performed on human HSCT grafts. The first study which began in 2015 and is ongoing. In this study we used small portions received under ethical committee approval from human donors to validate and optimize the process and show robustness and repeatability of the process. More than 200 ApoGraft samples were analyzed for the different effects on the various groups of cells (stem and mature immune) as well as their functional capabilities (such as migration, colony formation and anti-cancer activity). The samples represented 5% of a graft used for transplantation into patients. The grafts were processed in vitro and in vivo (mice) allowing stem cell production for transplantation using ApoGraft. The use of the ApoGraft in the pre-clinical setting resulted in a significant increase in the death of certain subpopulations of mature immune cells, primarily unique subsets of T Lymphocytes, without compromising the quantity and quality of stem cells.

The second study, which was initiated in the first quarter of 2017, is a Phase I/II, dose escalating, 4-cohort, open label clinical trial of up to twelve patients designed to evaluate the safety, tolerability and efficacy of functionally selected donor derived mobilized peripheral blood cells that underwent our ApoGraft process and were transplanted into patients with hematological malignancies in an allogeneic hematopoietic stem cell transplantation. The primary endpoint of the study is overall incidence, frequency and severity of adverse events potentially related to ApoGraft at 180 days from transplantation. The first patient was recruited for this trial in February, 2017 and in October 2018, we announced that the first six patients finished first month follow up and all these patients have shown 100% engraftment with no procedure related adverse events and that the first three patients of the trial completed the 180-day study period with full safety and tolerability. As of the date of this annual report, 8 patients have been treated with ApoGraft in the study. We expect to report interim results from the trial in the first half of 2019 and topline results from the trial in late 2019 or early 2020.

Patients who complete the Phase I/II study are given the option to enroll in a non-interventional long-term follow-up study for up to two years post-transplantation to assess incidence, grade and stage of acute GvHD and chronic GvHD, non-relapse related mortality, disease relapse/recurrence and overall survival.

We aim to commence a second human ApoGraft trial in the United States for patients with hematological malignancies in haploidentical HSCT (donors and patients are half matched), or haplo-HSCT, by the end of 2019. To this end, we are collaborating with Washington University for the initiation of this trial. The collaboration is being led by Professor John DiPersio, Director of the Center for Gene and Cellular Immunotherapy at Washington University School of Medicine and President of the American Society for Blood and Marrow Transplantation, and Professor Mark Schroeder, an expert in bone marrow transplantation in the Division of Oncology at Washington University School of Medicine. This clinical study aims to determine the safety and tolerability of ApoGraft for bone marrow transplantations with haplo-HSCT in a Phase I study.

Previously, in May 2017, we announced that the FDA provided us with pre-Investigational New Drug, or IND, meeting minutes supporting an IND submission for ApoGraft. We plan to file an IND with the FDA during 2019.

We are also conducting studies on mesenchymal stem cells, or MSC, derived from fat tissues. In October 2017, we announced positive results from a more than 20-patient study on the use of our selection platform technology on stem cells derived from fat tissues. The study comprised samples obtained via liposuction from over 20 adult patients and was conducted in collaboration with the Plastic Surgery Department and the Microsurgery and Plastic Surgery Laboratory of the Tel-Aviv Medical Center (Ichilov Hospital). Fat-derived stem cells were treated according to our protocols and have shown that our selection platform technology led to both an expansion of cells and an improvement in their unique cell activity and attributes. The ability of those cells to create colonies and differentiate into bone was enhanced significantly after only a short incubation. In addition, in October 2018, we announced that we achieved positive results on the use of human fat derived stem cells treated with the ApoGraft process in orthopedic treatments of animals.

We expect to announce in 2019 pre-clinical results for the use of human fat derived stem cells treated with ApoGraft in animal models. Furthermore, we plan on submitting an IND or IDE for the initiation of a Phase I/II trial of ApoGraft for anti-inflammatory indications and/or an orthopedic indications.

Our Strategy

We have developed a novel technology, the ApoGraft technology platform, for the functional selection of adult cells. This technology is expected to improve the safety and efficacy of regenerative medicine and stem cell therapies by allowing a cost effective method of achieving stem cells for any indication, in quality, quantity and competitive price. We aim to become the standard enabling technology for the enrichment of stem cells and manufacturing of any adult stem cells -based products for companies developing stem cell therapies and for researchers and academia engaged in adult stem cell research.

Key elements of our strategy to accomplish this objective include the following:

- **Achieve relatively quick validation of the use of our ApoGraft technology platform in a clinical setting.** We have chosen allogeneic HSCT for the treatment of hematological malignancies as our first target indication for our ApoGraft technology platform in order to clinically validate that our technology can efficiently select stem cells while eliminating harmful cells and consequently the medical complications such as GvHD. We believe hematopoietic cells transplantation to patients undergoing allogeneic HSCT can be dramatically improved. Based on our ApoGraft technology platform, we are currently developing the ApoTainer selection kit, an off the shelf stem cell selection kit, which we believe may significantly improve the therapeutic potential of allogeneic HSCT by addressing major complications that currently contribute to the high morbidity and mortality of the procedure. We believe that the concomitant reduction of toxicity of allogeneic HSCT will allow clinicians to undertake HSCT earlier in the blood cancer treatment routine. Typically, medical devices are expected to obtain relatively quicker validation from the FDA and the EMA when compared to pharmaceutical/ biological products. Based on our initial consultations with our U.S. and European regulatory consultants, we believe that we might only need to successfully complete a single pivotal study with a relatively small number of patients to obtain marketing approval of our ApoTainer selection kit for allogeneic HSCT. We believe such a study can be completed in approximately two to three years. However, there is no guarantee that the proposed pathway will be approved by the FDA or EMA, or that approval will occur as quickly as we hope, if at all. In addition, we believe that our product may achieve “breakthrough” designation with the FDA, enabling a fast track review and approval process by the FDA. However, there is no assurance that such designations will ever be obtained. Typically, the validation process for regular clinical development for standard cell therapy can take between eight and ten years. In comparison to the typical validation process timeline, we believe our technology platform may complete the validation process relatively quickly.

- **Leverage our scientific, clinical and regulatory expertise to build and advance our ApoGraft technology platform beyond the allogeneic HSCT setting.** Based on the validation of our ApoTainer selection kit for clinical use in the allogeneic HSCT setting, we intend to collaborate with other biotech companies to test the kit for other indications such as nonmalignant failures of the bone marrow (i.e. aplastic anemia), solid organ transplantation and auto-immune system disorders (such as Type 1 diabetes, Crohn’s disease, psoriasis, multiple sclerosis and lupus). We also intend to develop our ApoGraft technology platform for other sources of stem cells (e.g., cord blood and fat) and other types of stem cells — most notably mesenchymal and neural. We believe that by expanding the various applications, sources and types of stem cells that can be used with our technology, we will establish broad use of our ApoGraft technology platform.
- **Build a diversified product portfolio.** Beginning with the development of our ApoTainer selection kit as a medical device, which we believe will shorten the time to market, we intend to expand our product development and build a diversified product portfolio of ApoGraft based products for a broad spectrum of market segments, up to and including all production and research processes for stem cell based products. The pipeline of products is designed to address different markets beyond the clinical use such as products for research purposes and tools for manufacturing facilities for cell therapies and especially adult stem cells.
- **Selectively engage in strategic partnerships that establish our ApoGraft technology platform as the standard enabling technology for the enrichment of the stem cell population.** We ultimately seek to collaborate with other companies engaged in developing stem cell therapies. By incorporating our ApoGraft technology into their manufacturing process we will be able to significantly reduce their cost of manufacturing while improving the end products. As we believe our ApoGraft technology will significantly increase the yields of the first step of manufacturing (harvesting the stem cells) from any source of stem cells (i.e. blood, bone marrow, fat) and will result in a more purified bulk of stem cells, the next steps needed to reach the final products will be shorter, more efficient, less costly and result in a better product. In May 2018, we incorporated a US subsidiary and hired Andrew Sabatier as its Chief Business Officer to lead the business development activities from the US.

In the short term, we are currently focused on achieving the following critical milestones:

- **Advancing our clinical development plan:** We are currently enrolling patients to a Phase I/II study performed on cancer patients undergoing matched related allogeneic HSCT. This Phase I/II trial was approved by the Israeli Ministry of Health and is being conducted at the Rambam Medical Center and Hadassah Medical Center. In addition, we are preparing to commence a second human ApoGraft trial in collaboration with the Washington University School of Medicine under the leadership of Professor Dipersio and Professor Schroeder. This Phase I study using ApoGraft will be performed for the large unmet need of GvHD prevention in bone marrow transplantation of cancer patients undergoing haplo-HSCT.
- **Pathway to product prototype:** We are engaged in developing prototypes of our ApoTainer selection kit. We demonstrated a proof of concept for the binding of the apoptotic protein to a polymer while preserving the protein’s apoptotic activity. We tested a number of polymers and binding methods and selected the one best suited for manufacturing the stem cell selection kits.
- **Patent portfolio enhancement:** We are currently expanding our patent coverage from our current nine patent families and are applying for additional patents. By applying for additional patents for inventions created during development, we actively seek to widen and strengthen our patent portfolio. In addition, we are seeking relevant patents available for in licensing.

In the long term, we are focused on leveraging our key assets, including our intellectual property, our development team and our facilities, to advance our technologies and are pursuing strategic collaborations with members of academia and industry.

Regenerative Medicine and Cell Therapy

Our business focus is the development of technologies for the functional selection of stem cells in the field of regenerative medicine. According to Mason & Dunnill in *Regenerative Medicine* (2008, 3(1), 1-5), regenerative medicine is the process of replacing or regenerating human cells, tissues or organs to restore or establish normal function. Cell therapy as applied to regenerative medicine holds the promise of regenerating damaged tissues and organs in the body by rejuvenating damaged tissue and by stimulating the body’s own repair mechanisms to heal previously irreparable tissues and organs.

Medical cell therapies are classified into two types: allogeneic (cells from a donor) or autologous (cells from one's own body), with each offering its own distinct advantages. Allogeneic cells are beneficial when the patient's own cells, whether due to disease or degeneration, are not as viable as those from a healthy donor. The use of healthy donors' stem cells is severely limited by the accompanied immune cells of the donor which may attack cells or organs of the transplanted patient. This rejection is limited to adult cells with stem cells generally evading such rejection. Separation of the immune rejection causing cells from the stem cells is therefore the bottle neck of all stem cell based therapies.

Regenerative medicine can be categorized into major subfields as follows:

- **Cell Therapy.** Cell therapy involves the use of cells, whether derived from adults, children or embryos, healthy donors or patients, from various parts of the body, for the treatment of diseases or injuries. Therapeutic applications may include cancer vaccines, cell based immune-therapy, arthritis, heart disease, diabetes, Parkinson's and Alzheimer's diseases, vision impairments, orthopedic diseases and brain or spinal cord injuries. This subfield also includes the development of growth factors and sera and natural reagents that promote and guide cell development.
- **Tissue Engineering.** This subfield involves using a combination of cells with biomaterials (also called "scaffolds") to generate partially or fully functional tissues and organs, or using a mixture of technology in a bioprinting process. Some natural materials, like collagen, can be used as biomaterial, but advances in materials science have resulted in a variety of synthetic polymers with attributes that would make them uniquely attractive for certain applications. Therapeutic applications may include heart patch, bone re-growth, wound repair, replacement neo-urinary conduits, saphenous arterial grafts, inter-vertebral disc and spinal cord repair.
- **Diagnostics and Lab Services.** This subfield involves the production and derivation of cell lines that may be used for the development of drugs and treatments for diseases or genetic defects. This sector also includes companies developing devices that are designed and optimized for regenerative medicine techniques, such as specialized catheters for the delivery of cells, tools for the extraction of stem cells and cell-based diagnostic tools.

All living complex organisms start as a single cell that replicates, differentiates (into various tissues and organs) and perpetuates in an adult through its lifetime. Cell therapy is aimed at tapping into the power of cells to treat disease, regenerate damaged or aged tissue and provide functional as well as esthetic/cosmetic applications. The most common type of cell therapy has been the replacement of mature, functioning cells such as through blood and platelet transfusions. Since the 1970s, bone marrow and then blood and umbilical cord-derived stem cells have been used to restore immune system cells mainly after chemotherapy and radiation used to treat many cancers. These types of cell therapies have been approved for use world-wide and are typically reimbursed by insurance.

Researchers around the globe are evaluating the effectiveness of cell therapy as a form of replacement or regeneration of cells for the treatment of numerous organ diseases or injuries, including those of the brain and spinal cord. Cell therapies are also being evaluated for safety and effectiveness to treat heart disease, autoimmune diseases such as diabetes, inflammatory bowel disease and bone diseases. While no assurances can be given regarding future medical developments, we believe that the field of cell therapy is a subset of biotechnology that holds promise to improve human health, help eliminate disease and minimize or ameliorate the pain and suffering from many common degenerative diseases relating to aging.

Over the past number of years, cell therapies have been in clinical development to attempt to treat an array of human diseases. The use of autologous (self-derived) cells to create vaccines directed against tumor cells in the body has been demonstrated to be effective and safe in clinical trials. Dendreon Corporation's *Provenge* therapy for prostate cancer received FDA approval in early 2010. Since then, there have been several additional approvals including, Cleveland Cord Blood Center which received approval for Clevecord in 2016 indicated for use in unrelated donor hematopoietic progenitor cell transplantation procedures, and Kite Pharma which received in 2017 approval for its CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma. Kite Pharma was subsequently purchased by Gilead Sciences for \$11.9 billion. In 2018, Novartis launched Kymria - the first CAR-T cells product approved by the FDA and Tigenix received EMA approval for Alofisel, a stem cell therapy for Crohn's disease. Takeda Pharmaceutical completed the acquisition of Tigenix in 2018 for approximately \$600 million.

In January 2019, the FDA Commissioner and Director of CBER announced that the FDA is witnessing a surge of cell and gene therapy products entering early development, evidenced by a large upswing in the number of IND applications. Based on this activity, they indicated that the FDA anticipates that the number of product approvals for cell and gene therapies will grow in the coming years and that by 2020 the FDA will be receiving more than 200 INDs per year and that by 2025 they predict that the FDA will be approving 10 to 20 cell and gene therapy products a year. We believe that this will drive a huge surge in demand for cost-effective production of raw materials and cells.

Market for Cell-Based Therapies

According to a 2017 report by Grand View Research, the world stem cell market is expected to grow to \$15.6 billion in 2025 at a CAGR of 9.2%.

- **The global population is aging.** According to the United Nations Department of Economic and Social Affairs, 2 billion people will be aged 60 and older by 2050, which means an increased prevalence of age-related disease in general and chronic disease in particular. Heavily burdened healthcare systems are looking to regenerative medicine to provide therapies that treat the root causes of chronic diseases rather than just their symptoms.
- **Expansion of stem cell therapies.** Stem cell therapies are being extended to new and prevalent indications such as cardiovascular diseases, neurodegenerative diseases, and autoimmune diseases. The number of cell therapy companies that are currently in Phase II and Phase III trials has been gathering momentum, and we anticipate that new cellular therapy products will appear on the market within the next several years. As noted above, the FDA predicts that by 2025 the FDA will be approving 10 to 20 cell and gene therapy products a year.
- **Potential new source of stem cells.** The last decade has witnessed the emergence of umbilical cord cryopreservation for the storage of newborn blood for future medical use. This new market already affects the field of transplantations with a growing share of cord blood transplantations at the expense of autologous and allogeneic transplantations of hematopoietic cells. In addition, another source of stem cells is fat used for treatment of bone, cartilage and skeleton related diseases as well as for esthetic purposes.
- **Increasing government, strategic partner, and investor support for stem cell research and development.** According to the Alliance for Regenerative Medicine, globally, companies active in gene and cell therapies, and other regenerative medicines raised more than \$2.8 billion in the third quarter of 2018, a 59% increase over the same period in 2017; and \$10.7 billion in the first three quarters of 2018, a 40% increase year-over-year.

Our Current Focus: Proof of Concept of Our ApoGraft Technology Platform through the Treatment of Hematological Malignancies

Hematological malignancies (blood cancers) comprise a variety of lymphomas and leukemias. A very important treatment protocol for these malignancies involves the use of HSCT. According to the Worldwide Network for Blood & Marrow Transplantation, more than 50,000 HSCTs are performed yearly worldwide, of which 53% are autologous (using stem cells from the patient) and 47% are allogeneic (using stem cells from a donor). In the treatment of leukemia, an allogeneic procedure is usually preferred over autologous due to a higher risk of recurrence of the underlying disease.

HSCT, also known as bone marrow transplantation, relies on the ability of infused hematopoietic stem cells to engraft in the patient's bone marrow, multiply and differentiate into mature blood cells. However, the success of allogeneic HSCT strongly depends upon the degree of immune compatibility between the donor and the host cells. In the majority significantly high number of cases, the unavailability of fully matching donors results in complications due to GvHD. In the majority of cases, the unavailability of fully matching donors results in complications due to GvHD.

GvHD is a complication that often develops after a bone marrow or stem cell transplant. GvHD happens when transplanted cells in the donated bone marrow or stem cells (graft) regard the transplant patient's native cells (host) as foreign and attack and destroy them. Acute GvHD, which usually occurs up to 100 days post transplantation, is associated with diarrhea, rash, liver damage and, in severe cases, can be life-threatening. Chronic GvHD, which usually appears later than three months post transplantation, is associated with skin damage, oral and/or vaginal mucositis, and liver damage. GvHD is treated by repressing the immune system using steroids and chemotherapy. The treatment's adverse effects include increased exposure to infections, recurrent hospital admissions, damage to vital organs and, in some cases, secondary cancers. Both quality of life and life expectancy are significantly decreased in these patients. Unfortunately, many patients are nonresponsive to steroids. The patients that do respond to steroids suffer from frequent infections leading to recurrent antibiotic treatments and hospitalizations. These complications are associated with high mortality and morbidity and are a meaningful limiting factor for what would otherwise be the most suitable therapy for cancer and autoimmune diseases.

GvHD can be prevented by depletion of the T-cell population from the donor graft prior to transplantation. Methods used to capture and purge T-cells out of the donor graft include using anti-thymocyte globulin or Alemtuzumab, suicide gene therapy, cytotoxic agents and fusion proteins. However, T cells support HSCT engraftment and immune reconstitution and are potent initiators and mediators of graft versus tumor, or GvT, reactions. As such, purging T cells can result in increased risks of graft failure or delayed immune reconstitution leading to life threatening infection and/or reduced GvT response, increasing the chances of cancer recurrence.

Due to these and other complications and due to the extremely aggressive pre-treatment chemotherapy and irradiation conditioning regimens, allogeneic HSCT is usually used only when the patient faces life-threatening danger. If allogeneic HSCT could be made safer, it could be used far earlier and more frequently for even more effective treatment of blood cancers. There is widespread awareness of the need for improved immune-system management technologies for HSCT — both to improve outcomes of transplantations that have already taken place and to make transplantation safe enough to become appropriate for older patients and those with earlier-stage diseases.

The use of HSCT has been tested and found to be effective for autoimmune diseases, such as juvenile diabetes, Crohn's disease and lupus, with the inherent toxicity of HSCT being the major drawback from further use. A safer HSCT could be used for these indications as well as creating immune tolerance for organ transplantation.

We have therefore chosen allogeneic HSCT for the treatment of hematological malignancies as our first target indication for our ApoGraft technology platform in order to clinically validate that our technology can efficiently select stem cells while eliminating harmful cells and their associated medical complications caused by GvHD. However, while GvHD has a sizeable market share with an unmet clinical need that we seek to address, we consider the validation of our technology as an important driver of a much broader utility of our technology platform.

An Unmet Need: Efficient Stem Cell Selection

Typically, there is a very small number of stem cells in the source tissue and, once removed from the body, these cells have the propensity to differentiate and lose their "stemness". Generation of large quantities of stem cells is, therefore, very challenging. This scarcity of stem cells within the biological donor samples is a serious obstacle to regenerative medicine and stem cell companies, both in research and in production settings. In addition to stem cell scarcity, another critical problem is the presence in the donor sample of mature cells that trigger immune response and create the major adverse effects associated with transplantation.

There are currently two main methods for attaining a critical mass of stem cells:

- **Morphological stem cell selection:**

Negative selection approach: Elimination of the cells including those that contribute to engraftment, usually T cells. It uses T cell-specific antigens common to all T cells and therefore indiscriminately eliminates all T cells, including the ones responsible for engraftment support and combating tumors. The clinical outcome is reduced engraftment and reoccurrence of the tumor.

Positive selection approach: Retains the stem cells in the graft using only one of the determinants found on stem cells and progenitor cells and therefore a significant number of reconstituting capable cells are discarded. It has been clinically shown that the loss of reconstituting capable cells significantly reduces engraftment.

Both of these approaches have a poor efficacy/toxicity ratio.

- **Stem cell population expansion:**

Most companies expand stem cell numbers in a culture. However, expansion of the reconstituting capable cells while maintaining their level of differentiation is a major challenge. A high number of cells is required initially, as well as a very long culturing time (weeks) during which sterility must be maintained and differentiation avoided. The methodology is very expensive and requires specialized equipment that is not widely available. Moreover, the regulatory demands related to long-term culturing create a significant challenge for these companies.

In short, we believe the prevailing methodologies for stem cell enrichment/expansion in the graft do not adequately meet the need to enrich and purify the biological sample prior to transplantation. We believe our novel ApoGraft technology platform that quickly and effectively enriches the stem cell population while eliminating the unwanted cells in a biological sample will contribute significantly to the growth of the stem cell therapy market.

Our first target market for our ApoGraft technology platform is allogeneic HSCT for hematological malignancies. According to the Center for International Blood & Marrow Transplant Research, over 8,000 allogeneic HSCTs were performed in the United States in 2015. A 2013 survey conducted by the European Group for Bone Marrow Transplantation in 48 countries (39 European and 9 affiliated) showed that over 10,500 allogeneic HSCTs were performed for leukemia and for lymphoma. We believe that beyond the value of proving and validating our technology platform, these numbers represent a substantial market opportunity for us to prove the benefits of our ApoGraft technology platform.

Our Proprietary Stem Cell Technology Platform

We believe our innovative ApoGraft technology platform represents a potential breakthrough in the field of regenerative medicine through the functional selection of stem cells.

Our technology is based on a decade of research in the field of stem cells in general and hematopoietic stem cells in particular conducted by Dr. Nadir Askenasy, our former Chief Technology Officer. The concept of functional selection suggests that by using functional assays, which are based on the physiological features of stem cells, one can achieve dual goals: (i) the elimination of non-stem cells that are responsible for the immune triggering and most of the clinical adverse effects, and (ii) the achievement of a larger and better population of stem cells. We believe this dual effect will allow for safer and improved clinical outcome of transplantations and enable the whole regenerative (transplantation) segment to achieve its full potential.

Stem cells flourish in an environment where there are signals of apoptosis. Apoptosis is the process of programmed cell death and is a vital part of physiological development and maintenance. Because of their major role in the reconstitution of damaged tissue, stem cells are attracted to what are often characterized as disaster areas in which there are very high levels of apoptotic activity and apoptotic-inducing agents. Our research has demonstrated that stem cells are resistant to apoptotic stimulation by the physiological molecules that cause mature cells to self-destruct. We have chosen this *functional* characteristic of stem cells to use apoptosis-inducing proteins to more efficiently select stem cells while eliminating harmful cells and their associated medical complications.

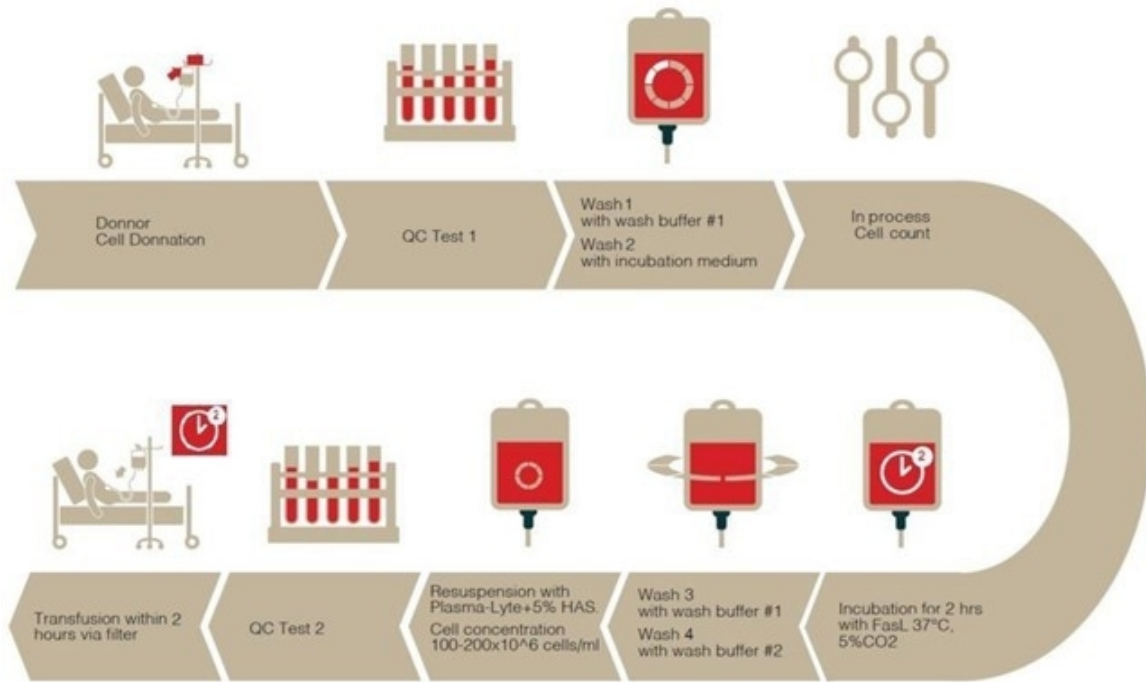
Our preclinical studies to date have shown that the differential sensitivity to the apoptosis signals allows functional selection of the stem cells. While stem and progenitor cells fully maintain their reconstitution and anti-tumor activity, the apoptosis sensitive mature immune cells (mainly the T lymphocytes) are eliminated. We believe that this effect will be translated to reduction of GvHD, improved graft acceptance and a reduction in treatment complications and costs.

The ApoGraft Process

To achieve functional selection of stem cells utilizing our ApoGraft technology platform, we have developed the ApoGraft process, which is intended for the prevention of GvHD in patients with hematological malignancies receiving a transplant of allogeneic, mobilized peripheral blood hematopoietic stem and progenitor cells. Following collection of the cells from a matched related donor, the donor graft is incubated for 2 hours in the presence of FasL, washed twice and transplanted via intravenous administration. FasL, also known as CD95L, is a type-II transmembrane protein that belongs to the tumor necrosis alpha family. The binding of FasL with its receptor induces in mature cells apoptosis (programmed cell death) that plays an important role in the development, homeostasis, and function of the immune system (and most cells of all multi-cellular organisms).

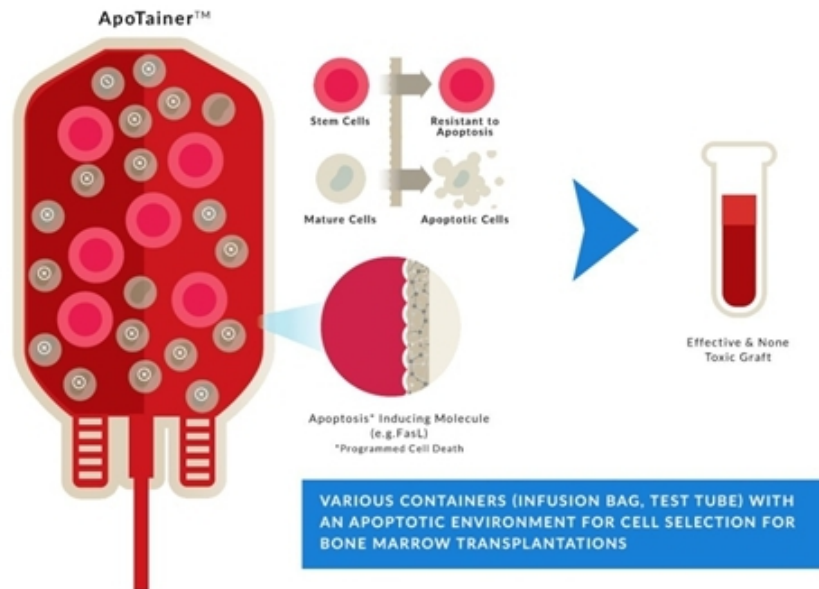
The apoptotic inducer used in Collect's ApoGraft process is based on a FasL protein known by its commercial name Mega-FasL. Apo010 (the Mega-FasL based clinical grade material) is a recombinant, soluble protein. This protein has been developed to mimic the natural occurring FasL clustering that activates its receptor and leads to apoptosis in susceptible cell populations.

The ApoGraft process is illustrated below:



ApoTainer Selection Kit

Our first product, the ApoTainer selection kit, is being developed as an easy to use, cost effective, off the shelf stem cell selection kit for clinical use to reduce GvHD following human allogeneic HSCT.



With internal apoptotic inducing capabilities and mimicking of the normal physiological conditions where stem cells can migrate to areas of destruction (where apoptotic triggering molecules are abundant) and, once there, proliferate and differentiate into the needed tissue and organ, the ApoTainer selection kit is designed to create a microenvironment intended to induce apoptosis by thereby eliminating the mature immune cells and preserving the hematopoietic stem and progenitor cells.

Since FasL is active when immobilized, we developed an ApoTainer selection kit where the FasL is immobilized to the surface of paramagnetic beads thereby creating an enlarged surface where more FasL molecules are able to interact with the Fas receptor on the immune cells. This immobilization to the paramagnetic beads also creates a unique advantage of being able to eliminate the need to discard the FasL from the graft before transplantation thereby shortening and simplifying the whole ApoGraft manufacturing. We anticipate that with the new ApoTainer we could reduce the donor-patient time to 3-4 hours, which may in turn improve the viability of the graft and increase the efficiency of the bone marrow transplantation procedure. The fact that all the process will be carried in a closed single compartment is expected to reduce the infrastructure needed today for bone marrow transplantation and allow for the expansion of bone marrow transplantation usage.

The ApoTainer selection kit is currently being designed to be used for allogeneic HSCT procedures for patients suffering from hematological malignancies in which the donor graft of cells is incubated in the infusion bag for a number of hours and expected to cause the mature GvHD-causing cells expressing the Fas receptor to bind to the beads-bound FasL and undergo apoptosis while the hematopoietic stem cells remain viable. The ApoTainer selection kit thus is expected to harness the differential effect of the apoptotic microenvironment on mature cell and stem cell populations, producing an enriched population of stem cells that are then transfused to the patient.

Preliminary studies conducted by us have shown that selective polymers coated with specific materials in a specific process create an optimal container enabling positive biological activity of FasL while tightly bound. We believe that this polymer-binder-FasL complex is the basis not only for the ApoTainer selection kit as currently in development, but also for a line of containers with different designs and sizes to be used for different applications.

During 2018, we developed FasL-coated paramagnetic beads for the ApoTainer. The use of FasL-coated paramagnetic beads significantly increases the active surface allowing a dramatic increase of interactions between the selecting agent and the cells. Further, such testing showed that the outcome increases specific elimination of certain (but not all) of the non-stem cells while full preservation of the number and function of the stem and progenitor cells. Further, during 2018 we were able to optimize the beads size, coating technology, prevention of the release of FasL into the medium, all while preserving the biological activity observed in our ongoing human clinical trial.

Preclinical Studies

As part of our in vitro studies, and prior to animal studies, we performed experiments to determine which apoptotic molecules have the best differential effect on stem and non-stem cells. We have conducted 22 animal studies including murine to murine and human cells to murine transplantation models measuring the relevant effects (GvHD, GvL, mortality and engraftment). We have also tested various sources of human hematopoietic cells (mobilized peripheral blood, bone marrow and umbilical cord blood). Major preliminary findings include the following:

- Resistance to receptor-mediated apoptosis is an inherent characteristic of stem and progenitor cells;
- The ApoGraft process preserves stem and progenitor cells;
- Preservation of successful engraftment (95% engraftment in experiments performed by a CRO);
- Demonstrated preservation of anti-tumor activity;
- Apoptosis-insensitive progenitors are privileged for engraftment through competitive advantage over the apoptosis-sensitive differentiated cells;
- Using the most stringent conditions for GvHD, there was a statistically significant reduction in mortality rate (20–100% to <10%); and
- Significant reduction of cells that attack the immune system.

We believe these preliminary findings support our product claim for:

- Selection of stem and progenitor cells based on insensitivity to receptor-mediated apoptosis from all sources;

- Ex vivo selective depletion of GvHD causing cells;
- Accelerated engraftment by ex vivo treatment of umbilical cord blood; and
- Induction of tolerance to grafts and suppression of autoimmunity.

In August 2015, we initiated a full preclinical Good Laboratory Practice toxicity study designed to test safety and engraftment outcome in a murine model ahead of our first planned clinical trial. Complete biochemical and histology evaluation was performed by a CRO as per regulatory requirements. In December 2015, we announced that results from this study showed that, while the control group had a 50% death rate, the group that was transplanted with bone marrow that underwent our ApoGraft process had no deaths. In addition, with respect to additional parameters, such as clinical signs, weight and histological analysis, no toxicity was found.

Non-Interventional Clinical Studies

We are performing a study on human HSCT grafts. This study first began in 2015 and is ongoing. In this study we used small portions received under ethical committee approval from human donors to validate and optimize the process and show robustness and repeatability of the process. More than 200 ApoGraft samples were analyzed for the different effects on the various groups of cells (stem and mature immune) as well as their functional capabilities (such as migration, colony formation and anti-cancer activity). The samples represented 5% of a graft used for transplantation into patients. The grafts were processed in vitro and in vivo (mice) allowing stem cell production for transplantation using ApoGraft. The use of the ApoGraft in the pre-clinical setting resulted in a significant increase in the death of certain subpopulations of mature immune cells, primarily unique subsets of T Lymphocytes, without compromising the quantity and quality of stem cells.

We are also conducting studies on MSC derived from fat tissues. In October 2017, we announced positive results from a more than 20-patient study on the use of our selection platform technology on stem cells derived from fat tissues. The study comprised samples obtained via liposuction from over 20 adult patients and was conducted in collaboration with the Plastic Surgery Department and the Microsurgery and Plastic Surgery Laboratory of the Tel-Aviv Medical Center (Ichilov Hospital). Fat-derived stem cells were treated according to our protocols and have shown that our selection platform technology led to both an expansion of cells and an improvement in their unique cell activity and attributes. The ability of those cells to create colonies and differentiate into bone was enhanced significantly after only a short incubation. In addition, in October 2018, we announced that we achieved positive results on the use of human fat derived stem cells treated with the ApoGraft process in orthopedic treatments of animals.

We expect to announce in 2019 pre-clinical results for the use of human fat derived stem cells treated with ApoGraft in animal models. Furthermore, we plan on submitting an IND for the initiation of a Phase I/II trial of ApoGraft for anti-inflammatory indications and/or an orthopedic indications

First In Man Clinical Study

On September 12, 2016, we obtained the approval of the Israeli Ministry of Health to initiate a Phase I/II, dose escalating, 4-cohort, open label clinical trial of up to twelve patients designed to evaluate the safety, tolerability and efficacy of functionally selected donor derived mobilized peripheral blood cells that undergo our ApoGraft process in the prevention of acute GvHD in patients suffering from hematological malignancies that are undergoing allogeneic HSCT. The primary endpoint of the study is overall incidence, frequency and severity of adverse events potentially related to ApoGraft at 180 days from transplantation.

In the study, the graft is taken from the donor through standard apheresis and then the cells are exposed to short ex-vivo incubation with FasL and then undergo washing and centrifugation to remove the FasL. The resulting cells are then transfused to the patient according to routine myeloablative procedures, or therapeutic modalities, including, but not limited to, chemotherapy, radiotherapy and immunotherapy.

The study is being conducted in two tertiary bone marrow transplant centers in Israel (Rambam Medical Center in Haifa, Israel and Hadassah Medical Center in Jerusalem, Israel). The clinical trial has been conducted under approval from the local Institutional Review Board and the Israeli Ministry of Health at the medical centers compliant with the ICH-GCP, applicable Israeli MoH guidelines (2016) for the conduct of clinical trials, World Medical Association Declaration of Helsinki and applicable local regulations/guidelines.

The first patient was recruited for this trial in February, 2017 and in October 2018, we announced that the first six patients (cohorts I and II) finished first month follow up and all these patients have shown 100% engraftment with no procedure related adverse events and that the first three patients of the trial (cohort I) completed the 180-day study period with full safety and tolerability. As of the date of this annual report, 8 patients have been treated with ApoGraft in the study. We expect to report interim results from the trial in the first half of 2019 and topline results from the trial in late 2019 or early 2020.

Patients who complete the Phase I/II study are given the option to enroll in a non-interventional long-term follow-up study for up to two years post-transplantation to assess incidence, grade and stage of acute GvHD and chronic GvHD, non-relapse related mortality, disease relapse/recurrence and overall survival.

Planned U.S. Study

We aim to commence a second human ApoGraft trial in the United States for patients with hematological malignancies in haploidentical HSCT (donors and patients are half matched), or haplo-HSCT, by the end of 2019. To this end, we are collaborating with Washington University for the initiation of this trial. The collaboration is being led by Professor John DiPersio, Director of the Center for Gene and Cellular Immunotherapy at Washington University School of Medicine and President of the American Society for Blood and Marrow Transplantation, and Professor Mark Schroeder, an expert in bone marrow transplantation in the Division of Oncology at Washington University School of Medicine. This clinical study aims to determine the safety and tolerability of ApoGraft for bone marrow transplantations with haplo-HSCT in a Phase study.

Finding a donor remains a challenge for patients in need of an urgent HSCT. The ability to obtain half matched stem cells from any family member represents a significant breakthrough in the field. Haplo-HSCT is characterized by the nearly uniform and immediate better availability of a donor and the availability of the donor for post-transplant cellular immunotherapy. However, haplo-HSCT carries a high risk of GvHD and poor immune reconstitution when GvHD is treated prevented by all existing methods of vigorous ex vivo or in vivo T-cell depletion. Different treatment approaches are currently being explored to mitigate complications such as graft rejection, severe GvHD, and prolonged immune suppression. Our platform technology, ApoGraft, is based on certain findings to date that GvHD can be prevented. We therefore believe that the combination of haplo-HSCT with the ApoGraft process has the potential to improve the standard of care therapy in the field and potentially mitigate haplo-HSCT related complications.

Previously, in May 2017, we announced that the FDA provided us with pre-IND meeting minutes supporting an IND submission for ApoGraft. We plan to file an IND with the FDA during 2019.

MSC Studies

We are also conducting studies on MSC, derived from fat tissues. In October 2017, we announced positive results from a more than 20-patient study on the use of our selection platform technology on stem cells derived from fat tissues. The study comprised samples obtained via liposuction from over 20 adult patients and was conducted in collaboration with the Plastic Surgery Department and the Microsurgery and Plastic Surgery Laboratory of the Tel-Aviv Medical Center (Ichilov Hospital). Fat-derived stem cells were treated according to our protocols and have shown that our selection platform technology led to both an expansion of cells and an improvement in their unique cell activity and attributes. The ability of those cells to create colonies and differentiate into bone was enhanced significantly after only a short incubation. In addition, in October 2018, we announced that we achieved positive results on the use of human fat derived stem cells treated with the ApoGraft process in orthopedic treatments of animals.

We expect to announce in 2019 pre-clinical results for the use of human fat derived stem cells treated with ApoGraft in animal models. Furthermore, we plan on submitting an IND or IDE for the initiation of a Phase I/II trial of ApoGraft for anti-inflammatory indications and/or an orthopedic indications.

Future Studies

We intend to undertake the following actions during the following twelve to eighteen months:

- File an IND for a Phase I study with the FDA and initiate the study during 2019;
- Complete a preclinical package for a Phase I/II ApoGraft clinical trial on stem cells derived from fat tissues;
- Complete the preclinical development of the first ApoTainer selection kits;
- Develop aseptic processing and determine ApoTainer selection kits shelf life;
- Produce initial batches of the ApoTainer selection kits for clinical trials; and
- Meet FDA and/or European regulatory authorities and submit a trial protocol for a clinical trial using the ApoTainer selection kit.

Regulatory Status

We plan to bring our ApoTainer selection kits to market for HSCT as a medical device subject to the primary jurisdiction of the CBER. The classification of our ApoTainer selection kits by the FDA as a drug, a medical device or a combination product depends upon, among other things, the regulatory definition of a drug and a device, their primary mode of action and the indications for use or product claims. In February 2019, we filed a Pre-RFD to the FDA to designate the Apotainer as a medical device under the regulation of the CBER. Under the Pre-RFD, the FDA will provide a preliminary, nonbinding assessment of the regulatory identity or classification of our ApoTainer selection kits and an assessment of which Center will regulate the product. We also believe that due to its novelty and being first in class this product could be classified as a “de-novo” which could allow for less clinical data before marketing approval. In certain territories (e.g. Japan) due to favorable regulatory conditions conditional marketing approval could be achieved before completion of full clinical development.

Collaborations

In June 2018, we entered into a collaboration and material transfer agreement with the denovoMATRIX group of the Technische Universität Dresden (TU Dresden), a leading center for stem cell research in Germany. According to the agreement, the team of denovoMATRIX employed by TU Dresden have conducted examinations into the tentative synergy between our ApoGraft and denovoMAtrix technology and evaluated collaborative development of products for regenerative medicine. The preliminary testing was performed and synergy between the two technologies have been demonstrated. Data supported improved mesenchymal stem cells growth when exposed to FasL embedded in denovoMAtrix matrix. Both sides agreed to negotiate in good faith a potential mutual development agreement, for the development of a stem cell related product.

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In July 2018, we entered into a collaboration agreement with Cell2in Inc., a South Korean company focused on improving the quality of cells. According to the agreement, the companies will conduct scientific evaluations combining ApoGraft with Cell2in’s proprietary identification technology FreSHtracer™ which monitors stem cell quality by utilizing a fluorescent dye to characterize their oxidative stress state. In December 2018, the Korea-Israel Industrial R&D Foundation (KORIL-RDF) approved a grant for the collaboration between Cellect and Cell2in, providing financing for the joint project.

Preliminary results from the collaboration include the following: (i) higher degree of stemness (both in Cell2in and standard assays) maintained through repeated expansions of bone marrow and umbilical cord derived mesenchymal stem cell, (ii) improved expansion of adipose derived mesenchymal stem cells in early and late passages, and significantly increased stemness of hematopoietic stem cells within two hours of the ApoGraft process.

Future Applications

Beyond the use of our ApoGraft technology platform in the allogeneic HSCT setting for the treatment of hematological malignancies as currently contemplated, we believe that our technology platform has the potential for a much broader set of usages:

- **Use of HSCT earlier in the blood cancer treatment protocol.** By reducing HSCT toxicity and other complications while increasing efficacy, we believe that our stem cell selection kits will allow clinicians to undertake HSCT earlier in the blood cancer treatment protocol.
- **Broadened use of HSCT to non-life threatening autoimmune disorders.** We are considering initiating clinical trials in autoimmune conditions where HSCT was proven to be beneficial but it was seldom used because of the inherent toxicity. We believe that if we are able to demonstrate significant reduction of inherent toxicity, this will help make HSCT eligible for treatment of diseases such as Type 1 diabetes, lupus, psoriasis, Crohn’s disease and the like.
- **Broadened use of HSCT to organ transplants.** It has been known for some time that allogeneic HSCT taken from the same donor enhances transplantation tolerance. This phenomenon has been observed not only in numerous animal models, but in humans as well. For example, several clinical trials have reported that kidney transplantation accompanied by a previous HSCT from the same donor was tolerated by the recipient’s immune system. We believe that our products could become the major adjunct therapy in any solid organ transplantation to allow tolerance.

- **Functional selection of cord blood.** Stem cells from the cord blood of newborns can be collected immediately after birth and preserved frozen. Currently, the main impediment of HSCT based on stem cells from cord blood is that the amount of cord blood is very limited. In combination with inefficient selection methods, the quantity of the collected stem cells is minimal. Therefore, the treatment is usually limited to children having low body mass. Physicians have tried using double cord blood and other methods which have resulted in new immune related adverse effects. Under ethical review board approval, we examined more than 150 samples of cord blood and showed that we can achieve approximately 400 times more stem and progenitor cells from any given samples. We believe this may open up the use of cord blood for adult patients in the future.
- **Stem cell expansion.** We already have preliminary indications that our ApoGraft technology platform greatly improves the efficiency of the stem cell expansion process by increasing the initial number of cells that undergoes expansion. Therefore, we believe that companies that currently use stem cell expansion will have a major advantage if our selection process is integrated as the first step in their manufacturing process.
- **Tissue and organ engineering.** One of the objectives of regenerative medicine is to enable the use of stem cells as a reservoir for organ and tissue engineering and, ultimately, transplantation. The goal is that the patient will be able to accept organs or tissues engineered from foreign stem cells. These emerging technologies rely on a sufficient number of stem cells from the donor and the separation of those cells from the donor's immune system in order to avoid rejection. We believe that our functional stem cell selection process can be the optimal solution for such needs.
- **Mesenchymal stem cells.** Develop the use of fat derived mesenchymal stem cells under FasL treatment for various indications including immune tolerance, orthopedic and dermato-cosmetic indications.
- **Reduce treatment related toxicity of T cell immunotherapies such as CAR-T cells.** We have commenced a collaboration with a leading academic group, in which the effect of the ApoGraft on reducing toxicity related to CAR-T treatment is tested.

Research and Development

Our core technology was originally derived from research conducted by the research group of Dr. Nadir Askenasy. Our research and development activities have been focused on additional animal models of a variety of diseases, experiments to determine the mechanism of action of our ApoGraft technology platform, and toxicology testing. Based on these preclinical programs we have begun clinical testing of products based on our ApoGraft technology platform in humans. During the years ended December 31, 2016, 2017 and 2018, we incurred approximately \$2.1 million, \$3.3 million, \$3.6 million respectively in expenses on company research and development activities.

Raw Materials and Suppliers

Although most raw materials for the ApoGraft technology platform is readily obtainable from multiple sources, we know of only two manufacturers of clinical grade FasL (the apoptotic inducing signal), Oncology Ventures A/S and Swiss Biotech Center, or SBC. In July 2018, we entered into a strategic manufacturing and supply agreement with SBC to secure production of clinical grade FasL protein in which the clone is originated from Adipogen International. According to the agreement, SBC granted to us exclusivity to the FasL protein developed by SBC for a period of five years and agreement further provided for the production of clinical batches of the FasL protein for our planned US clinical trials. The parties contemplate expanding production capacity to meet future needs including any marketing and collaborations with licensors of Collect technology. In January 2019, we announced that we have concluded the scale-up development and manufacturing of clinical grade FasL in collaboration with SBC. We believe we have secured sufficient quantity of the FasL needed for the manufacturing for our clinical trial due to start in the U.S. by the end of 2019.

We have previously experienced delays in the supply of FasL for our planned second human ApoGraft trial. If our current supplier of FasL or any other supplier suffers a major natural or man-made disaster at its manufacturing facility, or if they otherwise cease to supply to us, then this could result in further delays in our clinical studies and may delay product testing and potential regulatory approval until a qualified alternative supplier is identified. With respect to other raw materials for the ApoGraft technology platform, although multiple sources of supply exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers.

If our manufacturers or we are unable to purchase any key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Manufacturing

We do not own or operate, and currently have no current plans to establish, any manufacturing facilities. We rely on third-party outsourcing arrangements for our ApoTainer selection kits that we are developing as well as other preclinical testing activities. For clinical testing purposes, we intend to rely on third-party outsourcing arrangements as well. Upon completion of development, we may either continue to rely on third-party outsourcing arrangements or build a manufacturing facility either on our own or together with a strategic partner. We are no longer pursuing our collaboration with Entegris Inc. under a previously entered into Joint Product Development Agreement.

Competition

The field of regenerative medicine is expanding rapidly, in large part through the development of cell-based therapies and/or devices designed to isolate cells from human tissues. As the field grows, we face, and will continue to face, increased competition from pharmaceutical, biopharmaceutical, medical device and biotechnology companies, as well as academic and research institutions and governmental agencies in the United States and globally. Most regenerative medicine efforts involve sourcing adult stem and regenerative cells from tissues such as bone marrow, placental tissue, umbilical cord and peripheral blood. However, a growing number of companies are using adipose tissue as a cell source.

With the growing number of companies working in the cell therapy field, we, either now or in the future, will be forced to compete across several areas, including equity and capital, clinical trial sites, enrollment of patients in clinical trials, corporate partnerships, skilled and experienced personnel and commercial market share. Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We cannot with any accuracy forecast when or if these companies are likely to bring cell therapies to market for indications such as bone marrow transplants which we are also pursuing.

There are currently two companies that lead the stem cell selection market with whom we directly compete. The first is Miltenyi, which dominates the hematopoietic stem cell selection market, using biomarkers to either enrich stem cells (positive selection of CD34+ cells) or deplete mature hematopoietic cells such as T cells from the biological sample (negative selection by monoclonal antibodies specific against T-cell receptor $\alpha\beta$), or CD3/CD19 depletion or CD45RA depletion, resulting in the enrichment of stem and progenitor cells. The second is Cytori, which sells a medical device known as the Celution® System that enables bedside access to adult adipose derived regenerative cells, or ADRCs, by automating and standardizing the extraction, washing, and concentration of a patient's own ADRCs for present and future clinical use. While Miltenyi is using morphological markers of stem cells to enrich the stem cell population, Cytori is using the physical properties of cells (in general) through centrifugal force for separation. We believe that both technologies result in less than optimal cell population both in terms of quantity and quality (purity) of the selected population of cells.

In addition, since we are developing our ApoTainer selection kits to improve the safety and efficacy of allogeneic HSCT, we also compete with companies developing treatments for GvHD. These companies include Athersys, Inc., Bellicum Pharmaceuticals Inc., Erytech Pharma SA, Fate Therapeutics Inc., Fortress Biotech Inc., (formerly Coronado Biosciences), Gamida Cell Ltd., or Gamida, Kiadis Pharma N.V., or Kiadis, MEDIPOST Co., Ltd., Mesoblast Ltd., or Mesoblast, MolMed S.p.A., and Pluristem Therapeutics Inc., or Pluristem.

In the general area of cell-based therapies, we may now or in the future compete on an indirect basis with a variety of companies, most of whom are specialty medical products or biotechnology companies that provide a finished stem cell product that has already undergone stem cell selection including, among others, Advanced Cell Technology, Inc., Arteriocyte Medical Systems Inc., Athersys, Baxter International Inc., Bioheart Inc., Caladarius Biosciences Inc., Nuo Therapeutics, Inc., Fibrocell Science Inc., Gamida, Genzyme Corporation, Harvest Technologies Corporation, In vivo Therapeutics Holdings Corp., Johnson & Johnson, Kiadis, Mesoblast, Neuralstem Inc., Ocata Therapeutics Inc., Osiris Therapeutics, Inc., Pluristem, Tigenix NV, and others. We believe, however, that many of these companies have the potential to become customers in the future of our ApoGraft technology platform in order to improve and enhance their in-house processes.

Intellectual Property

Our success depends in large part on our ability to protect our proprietary technology and to operate without infringing on the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright and trademark laws, as well as confidentiality agreements, licensing agreements and other agreements, to establish and protect our proprietary rights. Our success also depends, in part, on our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing on any third-party patent, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities.

To protect our proprietary functional cell selection technology platform and other scientific discoveries, we have a wide family of patents and patent applications. These patents cover other stem cell related inventions but mainly our functional selection methodology, products and methods of use. The full published domain is further described below:

- A patent entitled “Method of Inducing Immune Tolerance via Blood/Lymph Flow-Restricted Bone Marrow Transplantation” was granted in the United States. If the appropriate maintenance fees are paid, the patent is expected to expire in April 2024 (including a 571 day patent term adjustment granted by the USPTO).
- A patent entitled “Methods of Selecting Stem Cells and Uses Thereof” was granted in the United States, Canada, Israel, India and Europe (validated in Denmark, France, Germany, Ireland, Netherlands, Switzerland and the United Kingdom). If the appropriate maintenance fees are paid, the patent is expected to expire in May 2027 in Israel, India and Europe and in September 2029 in the United States (including an 829 day patent term adjustment granted by the USPTO).
- A patent application entitled “Regulatory Immune Cells with Enhanced Targeted Cell Death Effect” was filed as a Patent Cooperation Treaty, or PCT, which entered national phase in the United States, Europe and Israel. A patent was granted in the United States, Israel and Europe and was validated in France, Germany, Ireland, Switzerland and the United Kingdom. If the appropriate maintenance fees are paid, the issued patents are expected to expire in July, 2031.
- A patent application entitled “Devices and Methods for Selecting Apoptosis-Signaling Resistant Cells and Uses Thereof” was filed as a PCT application and is now in national phase in Australia, Brazil, Canada, China, Europe, India, Japan, Korea, Russia, USA and Israel. A patent was granted in the United States, Japan, Korea, Russia and Europe (validated in Denmark, France, Germany, Ireland, Italy, Netherlands, Switzerland and the United Kingdom). With respect to the Australian application, the Australian Patent Office issued a Notification of Acceptance. If the appropriate maintenance fees are paid, these issued patents and the patents to be issued on the pending applications, if issued, are expected to expire in March, 2033.
- A patent application entitled “Activation of Hematopoietic Progenitors by Pre-transplant Exposure to Death Ligands” was filed as a PCT application and is now in national phase in Australia, Canada, China, Europe, India, Israel, Japan, Korea, and USA. If patents are issued from these applications, and if the appropriate maintenance fees are paid, these patents are currently expected to expire in October 2034.
- A patent application entitled “Selective Surface for, and Methods of, Selecting a Population of Stem and Progenitor Cells, and Uses Thereof” was filed as a PCT application and is now in national phase in Europe and USA. If patents are issued from these applications, and if the appropriate maintenance fees are paid, these patents are currently expected to expire in 2036.
- A patent application entitled “Methods for propagating mesenchymal stem cells (MSC) for use in transplantation” was filed as a PCT application and is now in national phase in Australia, Canada, China, Europe, India, Japan, Korea, Russia, USA and Israel. If patents are issued from these applications, and if the appropriate maintenance fees are paid, these patents are currently expected to expire in 2036.

We cannot assure that any of our pending patent applications will be issued, that we will develop additional proprietary products that are patentable, that any patents issued to us will provide us with competitive advantages or will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, we cannot assure that others will not independently develop similar products, duplicate any of our products, or design around our patents. U.S. patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using.

There is a risk that any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and declared invalid or infringing of third-party claims. For many of our pending applications, patent interference proceedings may be instituted with the USPTO when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent. At the completion of the interference proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex and highly contested, and the USPTO’s decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delay in obtaining a patent, and if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us. Third parties can file post-grant proceedings in the USPTO, seeking to have issued patent invalidated, within nine months of issuance. This means that patents undergoing post-grant proceedings may be lost, or some or all claims may require amendment or cancellation, if the outcome of the proceedings is unfavorable to us. Post-grant proceedings are complex and could result in a reduction or loss of patent rights.

There is uncertainty in the patent laws within and outside the United States and Israel as these are undergoing constant review and revisions through legislation and through court-made law. The laws of some countries may not sufficiently protect our proprietary rights. Third parties may attempt to oppose the issuance of patents to us by initiating opposition proceedings or institute proceedings to revoke the patents. Opposition or revocation proceedings against any of our patent application in one country could have an adverse effect on our corresponding issued patents or pending application in another country, e.g. in the United States or Israel. It may be necessary or useful for us to participate in proceedings intended to challenge and test the validity of our patents or our competitors' patents that have been issued in the United States, Israel and in many other jurisdictions. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

In addition to patent protection, we rely on unpatented trade secrets and proprietary technological expertise. We cannot assure you that others will not independently develop or otherwise acquire substantially equivalent techniques, somehow gain access to our trade secrets and proprietary technological expertise or disclose such trade secrets, or that we can ultimately protect our rights to such unpatented trade secrets and proprietary technological expertise. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Environmental Matters

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

Government Regulation

Any products we may develop and our research and development activities are subject to stringent government regulation. In the United States, these regulations include the Federal Food, Drug, and Cosmetic Act, or FDCA, and other federal and state statutes and regulations that govern the clinical and preclinical testing, manufacture, safety, effectiveness, approval, labeling, distribution, sale, import, export, storage, record-keeping, reporting, advertising, and promotion of our products. Product development and approval within this regulatory framework, if successful, will take many years and involve the expenditure of substantial resources. Violations of regulatory requirements at any stage may result in various adverse consequences, including the FDA's and other health authorities' delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions.

We are currently in the early clinical development stage and none of our products have been approved for sale in any market.

United States Regulatory Requirements

Regulation of Medical Devices Related to Licensed Blood or Cellular Products

The FDA is divided into various “Centers” by product type such as the Center for Drug Evaluation and Research, or CDER, CBER, or the Center for Devices and Radiological Health, or CDRH. Different Centers review drug, biologic, or device applications.

CBER regulates medical devices related to licensed blood and cellular products by applying appropriate medical device laws and regulations. Specifically, CBER regulates the medical devices involved in the collection, processing, testing, manufacture and administration of licensed blood, blood components and cellular products. The medical devices regulated by CBER are intimately associated with the blood collection and processing procedures as well as the cellular therapies regulated by CBER. CBER has developed specific expertise in blood, blood products and cellular therapies and the integral association of certain medical devices with those biological products supports the regulation of those devices by CBER.

After receiving FDA approval or clearance, an approved or cleared product must comply with postmarket safety reporting requirements applicable to the product based on the application type under which it received marketing authorization. In the case of current good manufacturing practices, or cGMP, the applicant may take one of two approaches: (1) complying with cGMP for each constituent part, or (2) a streamlined approach specific to combination products, subject to certain limitations.

We submitted and are awaiting feedback on a Pre-RFD submission to FDA made in February 2019. Under the Pre-RFD, the FDA will provide a preliminary, nonbinding assessment of the regulatory identity or classification of our ApoTainer selection kits and an assessment of which Center will regulate the product. Subject to the FDA’s response to our Pre-RFD, we plan to bring our ApoTainer selection kits to market for HSCT as a medical device subject to the primary jurisdiction of the CBER. In addition, we believe that due to its novelty and being first in class, this product could be classified as *de novo*, which could allow for less clinical data before marketing approval.

FDA Approval Process

The FDA extensively regulates, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and import and export of medical products. The FDA governs the following activities that we may perform or that may be performed on our behalf, to ensure that the medical products we may in the future manufacture, promote and distribute domestically or export internationally are safe and effective for their intended uses:

- product design, preclinical and clinical development and manufacture;
- product premarket clearance and approval;
- product safety, testing, labeling and storage;
- recordkeeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling and adverse event reporting, including reporting of deaths, serious injuries, malfunctions or other deviations; and
- recall of products, including repairs or remediation.

A new biologic must be approved by the FDA through the biologics license application, or BLA, process before it may be legally marketed in the U.S. The animal and other non-clinical data and the results of human clinical trials performed under an Investigational New Drug, or IND, application and under similar foreign applications will become part of the BLA. A new medical device must be cleared or approved by FDA through the premarket approval (PMA) or 510(k) clearance. For medical devices that require a PMA, clinical studies performed under an Investigation Device Exemption, or IDE, will become part of a PMA for a medical device. A combination biologic/device may be subject to standards of review for both CBER and CDRH. Although we have submitted a Pre-RFD for classification of the ApoTainer as a medical device, we discuss the respective regulatory approval pathways for both biologics and medical devices.

In the U.S., the FDA regulates biologics under the Public Health Service Act, or PHSA, and implementing regulations and medical devices under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations, respectively. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, requesting product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biologic or medical device may be marketed in the U.S. generally involves the following, though a more specific discussion of regulatory requirements for biologics and medical devices follows:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices, or GLP, or other applicable regulations;
- submission to the FDA of an IND or IDE which must become effective before human clinical trials may begin;
- Approval by an institutional review board, or IRB, representing each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug or device for its intended use;
- preparation and submission of a BLA or PMA to the FDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- satisfactory completion of any FDA audits of the clinical study sites to assure compliance with GCP, and the integrity of clinical data in support of the BLA or PMA;
- FDA review and approval of the BLA or PMA.

Once a biologic product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trials, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

Once a medical device product requiring a PMA is identified for development, it enters the feasibility study stage. For significant risk devices, including devices that are substantially important in diagnosing, curing, mitigating or treating disease or in preventing impairment to human health, sponsors must submit an investigational plan to FDA as part of the IDE. The IDE automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. An IDE sponsor typically must submit results of feasibility studies to FDA to receive approval to proceed with a pivotal study. A pivotal study is generally intended as the primary clinical support for a marketing application.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND or IDE, and progress reports detailing the results of the clinical trials must be submitted at least annually. In addition, timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board, or IRB, responsible for the research conducted at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials for biologics are typically conducted in three sequential phases that may overlap or be combined:

- *Phase I:* The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients.
- *Phase II:* This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase III:* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

Medical devices, however, typically rely on one or a few pivotal studies rather than Phase I, II, and III clinical trials.

Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, or IRB, for the relevant clinical trial sites and must comply with FDA regulations, including, but not limited to, those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patient's informed consent in a form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations.

The FDA, the IRB, or we could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits or a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Phase I, Phase II, and Phase III testing may not be completed successfully within any specified period, if at all. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States. Similarly, in Europe, the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

During the development of a new medical product, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND or IDE, at the end of Phase II, and before a BLA or PMA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III clinical trial that they believe will support approval of the new biologic. Similarly, sponsors typically use the end of feasibility studies to do the same for planning for their pivotal trial or trials for a medical device.

Clinical research involving the transplantation of cells or test articles derived from human fetal tissue into human recipients is subject to additional U.S. Department of Health and Human Services Office for Human Research Protections requirements. Because our ApoTainer stem cell selection kit uses autologous stem cell treatments, stem cells that are extracted of the patient and transplanted to the same patient, we believe these requirements do not apply to us.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of a biologic and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. For biologics, the manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. Before approving a BLA or PMA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHS in particular emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA.

Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMP and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

There are also specific approval requirements for both biologics and medical device products, respectively. Biologics and medical devices are also eligible for different forms of exclusivities and priority review, and combination products may be eligible for both. We discuss both regulatory paradigms below, as our ApoTainer stem cell selection kits product will implicate elements of each, largely at CBER's discretion to involve CDRH in the review and approval process.

U.S. Review and Approval of Biologics

In order to obtain approval to market a biological product in the United States, a marketing application must be submitted to the FDA that provides sufficient data establishing the safety, purity and potency of the proposed biological product for its intended indication. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the biological product to the satisfaction of the FDA.

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of a BLA requesting approval to market the product. The submission of a BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA initially reviews all BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA generally completes this preliminary review within 60 calendar days. The FDA may request additional information rather than accept a BLA for filing. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. The approval process is lengthy and often difficult, and the FDA may refuse to approve a BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Before approving a BLA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the BLA, or an approval letter following satisfactory completion of all aspects of the review process.

BLAs may receive either standard or priority review. Under current FDA review goals, standard review of an original BLA will be 10 months from the date that the BLA is filed. A biologic representing a significant improvement in treatment, prevention or diagnosis of disease may receive a priority review of six months. Priority review does not change the standards for approval, but may expedite the approval process.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness after BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized.

The Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted in 2012, made permanent the Pediatric Research Equity Act, or PREA, which requires a sponsor to conduct pediatric studies for most biologics with a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, BLAs and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before pediatric studies can begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit a required pediatric assessment within specified deadlines or fails to submit a timely request for approval of a pediatric formulation, if required.

Biologics Price Competition and Innovation Act of 2009

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to create an abbreviated approval pathway for two types of "generic" biologics — biosimilars and interchangeable biologic products, and provides for a twelve-year exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated; however if pediatric studies are performed and accepted by the FDA, the twelve-year exclusivity period will be extended for an additional six months. A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

U.S. Review and Approval of Medical Devices

Unless an exemption applies, medical device commercially distributed in the United States require either premarket notification, or 510(k) clearance, or approval of a premarket approval, or PMA, application from the FDA. While we anticipate CBER will be the lead Center in reviewing our product application, CDRH's review standards will likely apply to significant portions of the application.

The FDA classifies medical devices into one of three classes. Class I devices, considered to have the lowest risk, are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials (General Controls). Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device (Special Controls). Manufacturers of most Class II and some Class I devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA, requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. The submission of a 510(k) or PMA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances.

510(k) Clearance Pathway for Medical Devices

When a 510(k) clearance is required, an applicant is required to submit a 510(k) application demonstrating that our proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

Once filed, the FDA has 90 days in which to review the 510(k) application and respond. Typically, the FDA's response after reviewing a 510(k) application is a request for additional data or clarification. Depending on the complexity of the application and the amount of data required, the process may be lengthened by several months or more. If additional data, including clinical data, are needed to support our claims, the 510(k) application process may be significantly lengthened.

If the FDA issues an order declaring the device to be Not Substantially Equivalent, or NSE, the device is placed into a Class III or PMA category. At that time, a company can request a *de novo* classification of the product. *De novo* generally applies where there is no predicate device and the FDA believes the device is sufficiently safe so that no PMA should be required. The request must be in writing and sent within 30 days from the receipt of the NSE determination. The request should include a description of the device, labeling for the device, reasons for the recommended classification and information to support the recommendation. The *de novo* process has a 60-day review period. If the FDA classifies the device into Class II, a company will then receive an approval order to market the device. This device type can then be used as a predicate device for future 510(k) submissions. However, if the FDA subsequently determines that the device will remain in the Class III category, the device cannot be marketed until the company has obtained an approved PMA.

Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a PMA if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA were to disagree with any of our determinations that changes did not require a new 510(k) submission, it could require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA approval is obtained. If the FDA requires us to seek 510(k) clearance or PMA approval for any modifications, we may be required to cease marketing and/or recall the modified device, if already in distribution, until 510(k) clearance or PMA approval is obtained and we could be subject to significant regulatory fines or penalties.

Premarket Approval (PMA) Pathway for Medical Devices

While we believe that the medical device component of our ApoTainer stem cell selection kits will be subject to the 510(k) clearance pathway, FDA could evaluate our product under the PMA pathway if it believes the device component raises sufficiently complex or novel scientific issues.

A PMA application must be submitted to the FDA if the device cannot be cleared through the 510(k) process, or is not otherwise exempt from the FDA's premarket clearance and approval requirements. A PMA application must generally be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. During the review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of our or our third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. Once a PMA is approved, the FDA may require that certain conditions of approval be met, such as conducting a post-market clinical trial.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel.

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. Such trials generally require an application for an investigational device exemption, or IDE, which is approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject.

Breakthrough Device Designation

The FDA grants Breakthrough expedite development, assessment and review of medical devices that “provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and that represent breakthrough technologies; for which no approved or cleared alternatives exist; that offer significant advantages over existing approved or cleared alternatives, or the availability of which is in the best interest of patients.”

This status confers a number of benefits on the development path of medical devices. These include:

- a dedicated FDA team, including senior management engagement, to facilitate development of the device
- a defined process for resolving disputes that may arise between the sponsor and FDA
- a commitment to interactive and timely communication between FDA and the sponsor
- increased flexibility in clinical study design
- options for data collection in the post-market setting, in place of a full clinical study prior to approval
- priority review status, meaning that a sponsor's submissions will be placed at the top of the relevant review queue and receive additional FDA resources as needed
- expedited review and potential deferral of manufacturing and quality systems compliance audits
- advance disclosure to the sponsor of the topics of any consultation between the FDA and external experts or an advisory committee
- an opportunity for the sponsor to recommend external experts for such consultations
- assignment of FDA staff to address questions by institutional review committees concerning investigational use of the medical device
- any additional steps FDA deems appropriate to expedite the development and review of the medical device.

We plan to apply for a Breakthrough Designation for the container component of our ApoTainer selection kit.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our product, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as partial compensation for effective patent term lost due to time spent during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of a BLA, plus the time between the submission date of a BLA and the approval of that application, except that the period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug may be extended, and the extension must be applied for prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Pediatric exclusivity is another type of marketing exclusivity available in the U.S. FDASIA made permanent the Best Pharmaceuticals for Children Act, or BPCA, which provides, under certain circumstances, for an additional six months of marketing exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA, or a Written Request. If the Written Request does not include studies in neonates, the FDA is required to include its rationale for not requesting those studies. The FDA may request studies on approved or unapproved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described studies.

Orphan Drug Designation

We have received Orphan Drug Designation from FDA for our ApoGraft technology for the prevention of acute and chronic graft versus host disease (GvHD) in transplant patients. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not itself convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug, for the same designated orphan indication or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

The FDA also administers a clinical research grants program, whereby researchers may compete for funding to conduct clinical trials to support the approval of drugs, biologics, medical devices, and medical foods for rare diseases and conditions. A product does not have to be designated as an orphan drug to be eligible for the grant program. An application for an orphan grant should propose one discrete clinical study to facilitate FDA approval of the product for a rare disease or condition. The study may address an unapproved new product or an unapproved new use for a product already on the market.

Post-Approval Regulation of Biologics and Medical Devices

After a product is placed on the market, numerous regulatory requirements continue to apply. In addition to the requirements below, adverse event reporting regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Additional regulatory requirements include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- cGMP or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, validation, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our approved medical products;
- notice or approval of product or manufacturing process modifications or deviations that affect the safety or effectiveness of one of our approved medical products;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the medical product;

- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

A biologic product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the U.S. Federal Trade Commission, or FTC, and by state regulatory and enforcement authorities. Promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. Furthermore, under the federal U.S. Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Failure by us or by our third-party manufacturers and suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusing to grant export approval for our products; or
- criminal prosecution.

Human Cells, Tissues, and Cellular and Tissue-Based Products Regulation

Under Section 361 of the PHSA, the FDA issued specific regulations governing the use of human cells, tissues and cellular and tissue-based products, or HCT/Ps, in humans. Pursuant to Part 1271 of Title 21 of the Code of Federal Regulations, or Part 1271, the FDA established a unified registration and listing system for establishments that manufacture and process HCT/Ps. The regulations also include provisions pertaining to donor eligibility determinations; current good tissue practices covering all stages of production, including harvesting, processing, manufacture, storage, labeling, packaging, and distribution; and other procedures to prevent the introduction, transmission, and spread of communicable diseases.

The HCT/P regulations strictly constrain the types of products that may be regulated solely under these regulations. Factors considered include the degree of manipulation, whether the product is intended for a homologous function, whether the product has been combined with noncellular or non-tissue components, and the product's effect or dependence on the body's metabolic function. In those instances where cells, tissues, and cellular and tissue-based products have been only minimally manipulated, are intended strictly for homologous use, have not been combined with noncellular or nontissue substances, and do not depend on or have any effect on the body's metabolism, the manufacturer is only required to register with the FDA, submit a list of manufactured products, and adopt and implement procedures for the control of communicable diseases. If one or more of the above factors has been exceeded, the product would be regulated as a drug, biological product, or medical device rather than an HCT/P.

Management believes that Part 1271 requirements do not currently apply to us because we are not currently investigating, marketing or selling cellular therapy products. If we were to change our business operations in the future, the FDA requirements that apply to us may also change and we would potentially need to expend significant resources to comply with these requirements.

Federal Regulation of Clinical Laboratories

The Clinical Laboratory Improvement Amendments (“CLIA”) extends federal oversight to clinical laboratories that examine or conduct testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of disease or for the assessment of the health of human beings. CLIA requirements apply to those laboratories that handle biological matter. CLIA requires that these laboratories be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to biennial inspections, and remit fees. The sanctions for failure to comply with CLIA include suspension, revocation, or limitation of a laboratory’s CLIA certificate necessary to conduct business, fines, or criminal penalties. Additionally, CLIA certification may sometimes be needed when an entity desires to obtain accreditation, certification, or license from non-government entities for cord blood collection, storage, and processing. However, to the extent that any of our activities require CLIA certification, we intend to obtain and maintain such certification and/or licensure.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we obtain regulatory approval. Sales of any of our products, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a medical product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the medical product once coverage is approved. Third-party payors may limit coverage to medical drug products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Our products may not be considered medically necessary or cost-effective. A payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of medical products have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription medical products. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the drug candidates that we are developing and could adversely affect our net revenue and results.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union (EU) provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription medical products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the PPACA was enacted in the United States in March 2010 and contains provisions that may reduce the profitability of medical products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been judicial and congressional challenges to the PPACA, as well as efforts by the Trump Administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. However, to date, the Executive Orders have had limited effect and the Congressional activities have not resulted in the passage of a law repealing or replacing the PPACA. If a law is enacted, many if not all of the provisions of the PPACA may no longer apply to prescription medical products. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how any future products are paid for and reimbursed by government and private payers our business could be adversely impacted. On December 14, 2018, a federal district court in Texas ruled that the PPACA is unconstitutional as a result of the Tax Cuts and Jobs Act, the federal income tax reform legislation previously passed by Congress and signed by President Trump on December 22, 2017, that eliminated the individual mandate portion of the PPACA. The case, *Texas, et al, v. United States of America, et al.*, (N.D. Texas), is an outlier, and the ruling has been stayed by the ruling judge. We are not able to state with any certainty what will be impact of this court decision on our business pending further court action and possible appeals.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If we ever obtain regulatory approval and commercialization of ApoTainer or any future product candidates, these laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of ApoTainer or any future product candidates may be. Further, the Deficit Reduction Act of 2010, directed CMS to contract a vendor to determine "retail survey prices for covered outpatient drugs and biologics that represent a nationwide average of consumer purchase prices for such drugs and biologics, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available)." This survey information can be used to determine the National Average Drug Acquisition Cost, or NADAC. Some states have indicated that they will reimburse based on the NADAC and this can result in further reductions in the prices paid for various outpatient drugs and biologics.

On December 14, 2018, a federal district court in Texas ruled that the PPACA is unconstitutional as a result of the Tax Cuts and Jobs Act, the federal income tax reform legislation previously passed by Congress and signed by President Trump on December 22, 2017, that eliminated the individual mandate portion of the PPACA. The case, *Texas, et al, v. United States of America, et al.*, (N.D. Texas), is an outlier, and the ruling has been stayed by the ruling judge. We are not able to state with any certainty what will be impact of this court decision on our business pending further court action and possible appeals.

In the fourth quarter of 2018, the Trump Administration announced initiatives that it asserted are intended to result in purportedly lower drug prices. The first initiative, announced on October 15, 2018, involved the plan to a new federal regulation that would require pharmaceutical manufacturers to disclose the list prices of their respective prescription drugs and biologics in their television advertisements for their products if the list price is greater than \$35. With respect to the second initiative, on October 25, 2018, the Centers for Medicaid and Medicare Services gave Advance Notice of Proposed Rulemaking to propose the implementation of an "International Pricing Index" model for Medicare Part B drugs and biologics (single source drugs, biologicals, and biosimilars). Public comments were due on December 31, 2018 with a proposed rule theoretically being offered as early as Spring 2019 with target implementation of a five year pilot program beginning in Spring 2020. While these initiatives have not been put into effect, we are not in a position to know at this time whether they will ever become law or what impact the enactment either of these proposals would have on our business.

In February 2019, the Department of Health and Human Services has proposed a regulation that would significantly restrict the availability of certain regulatory safe harbors under the federal Anti-Kickback Statute that are used to facilitate certain types of transactions between manufacturers and pharmacy benefits managers that play a significant role in the pharmaceutical distribution chain. These changes to the Discount Safe Harbors available under the Anti-Kickback Statute would reduce some of the protections currently available to manufacturers that pay negotiated rebates to pharmacy benefits managers in exchange for these “PBMs” agreeing to include drugs and biologics on the formularies of the PBM’s downstream customers, primarily the health plans that insure patients for both private commercial plans and government-sponsored plans. While we do not know whether the Trump Administration will be successful in implementing this proposed regulation, its successful implementation could have an impact on both our commercial supply arrangements with health plans and our supply arrangements to health plans that serve beneficiaries of federal health care programs such as Medicare Part D.

As part of its reform of the 340B discount drug program, on October 31, 2018, the Health Resources and Services Administration at the U.S. Department of Health and Human Services, or HHS, issued a notice of proposed rulemaking to move up the effective date of a final rule that would give HHS authority to impose Civil Monetary Penalties on pharmaceutical manufacturers who knowingly and intentionally charged a covered entity more than the statutorily allowed ceiling price for a covered outpatient drug or biologic. The final rule is intended to encourage compliance by manufacturers in offering the mandatory 340B ceiling purchase price to eligible purchasers, such as certain qualified health systems or individual hospitals.

Various states, such as California, have also taken steps to consider and enact laws or regulations that are intended to increase the visibility of the pricing of pharmaceutical products with the goal of reducing the prices at which pharmaceutical products are sold. Because these various actual and proposed legislative changes are intended to operate on a state-by-state level rather than a national one, we cannot predict what the full effect of these legislative activities may be on our business in the future.

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

Anti-Kickback and False Claims Laws

In addition to FDA restrictions on marketing of medical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the medical product industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal Anti-Kickback Statute, or AKS, prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between medical product manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the AKS are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

The Federal False Claims Act, or FCA, prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free products to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other Regulations

We may from time to time become subject to various local, state and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro-organisms and various radioactive compounds used in connection with our research and development activities. These laws include, but are not limited to, the U.S. Occupational Safety and Health Act, the U.S. Toxic Test Substances Control Act and the U.S. Resource Conservation and Recovery Act. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, there can be no assurances that accidental contamination or injury to employees and third parties from these materials will not occur.

Foreign Regulatory Requirements

International sales of medical products are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ.

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

In the EU, the regulatory environment depends on the regulatory status of product. At this point, it is likely that the ApoTainer selection kit would qualify as a medical device in the EU. However, the substance used in the ApoTainer may qualify as a pharmaceutical product. The ApoTainer selection kit would have to undergo a conformity assessment procedure as a medical devices and the substance would have to obtain a marketing authorization as a drug. It is also possible that treatment using the ApoTainer will be subject to further regulatory requirements. In particular, it is possible that the stem cell treatment itself may be considered the production of a drug and, therefore, would require a manufacturing authorization according to Dir. 2001/83/EC. Furthermore, the use of the ApoTainer selection kit may be subject to Member States' laws on transplantation.

With regard to medical devices, the current legal regime is based on the MDD and its implementation in the Member States as well as several guidance documents and regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Each EU Member State has implemented legislation applying these directives and standards at a national level. Other countries such as Switzerland have voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices. Devices that comply with the requirements of the laws of the relevant Member State applying the applicable EU directive are entitled to bear a CE mark and, accordingly, can be distributed throughout EU Member States as well as in other countries, e.g., Switzerland and Israel, that have mutual recognition agreements with the EU or have adopted the EU's regulatory standards.

The method of assessing conformity with applicable regulatory requirements varies depending on the classification of the medical device, which may be Class I, Class IIa, Class IIb or Class III. Normally, the method involves a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a device complies with applicable regulatory requirements. An assessment by a Notified Body in one country with the EU is required in order for a manufacturer to commercially distribute the device throughout the EU. In addition, compliance with ISO 13485, issued by the International Organization for Standardization, among other standards establishes the presumption of conformity with the essential requirements for CE marking. Certification to the ISO 13485 standard demonstrates the presence of a quality management system that can be used by a manufacturer for design and development, production, installation and servicing of medical devices and the design, development and provision of related services. In 2017, the new Regulation (EU) No. 745/2017 on medical devices (the Medical Device Regulation, or MDR) has been published and will enter into force three years later, i.e., in 2020. The MDR will result in several medical devices being classified in higher risk classes and therefore face elevated regulatory requirements. In addition, the MDR will generally elevate regulatory requirements to medical devices. As a result, it is likely that it will become more difficult to market medical devices and costs incurred for clinical evaluation, conformity assessment and post marketing surveillance will increase.

If one or more of our current or future products would have the status of a drug under the law of the EU or one or more of its Member States, regulatory requirements for such product(s) would be significantly higher. In particular, a drug can only be placed on the market if it has been authorized by the competent regulatory authority either under the EU centralized procedure, the decentralized or mutual recognition procedure or under a member State's national procedure. Marketing authorizations for drugs under all of the different authorization procedures are expensive and time consuming.

Even if the ApoGraft technology platform and/or the ApoTainer is considered a medical device, it is possible that the actions performed by the products may be considered manufacture of a drug. While HSCT is considered to be subject to regulatory requirements for medicinal products (drugs) in the EU, it is possible HSCT is also considered to be an advanced therapy medicinal product (ATMP), subject to even stricter regulations. With regard to the most basic version of HSCT, the EMA, has issued an opinion stating that it regarded these treatments as exempt from drug and ATMP regulations. This basic HSCT involves the extraction of adipose stem cells from a patient's subcutaneous area and their transplantation in the subcutaneous area elsewhere in the body of the same patient, if the treatment is performed in one doctor visit, the cells have the same function where they are extracted as where they are transplanted, and they are not treated in any way between extraction and transplantation. This opinion does not apply to stem cell treatments that deviate from this basic version in one or several aspects. Consequently, other HSCT may qualify as drug treatments or as tissue preparations and a market authorization or manufacturing approval may be required. If there is doubt as to whether a stem cell treatment is considered a drug or tissue preparation, it is possible to obtain a statement with regard to the product status from the EMA Committee for Advanced Therapies (CAT). Whether EMA CAT would qualify a HSCT as a drug and/or an ATMP depends on several aspects, including the question whether the use of the stem cells is homologous and whether or not the stem cells have been substantially manipulated between their extraction and their transplantation. Furthermore, the treatment may be subject to EU laws on human tissues including Dir. 2004/23/EC setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and related legal framework on EU and/or Member State level.

However, even if EMA CAT does not consider the treatment a drug and/or an ATMP treatment, it is possible that competent authorities in the Member States nevertheless qualify the treatment as a drug and/or an ATMP and make its performance subject to a marketing authorization and/or manufacturing authorization on their territory.

Sales and Marketing

During 2017, we launched a business development campaign. We believe that interim results from our ongoing Phase I/II study will help validate our technology platform and qualify our technology for out licensing to companies interested in improving their manufacturing process of adult stem-cell based products. In May 2018, we incorporated a US subsidiary and hired Andrew Sabatier as its Chief Business Officer to lead the business development activities from the US. We are actively seeking to enter into licenses on a non-exclusive basis to various stem cells based companies.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are currently not a party to any material legal or administrative proceedings and except as set forth below, are not aware of any pending or threatened material legal or administrative proceedings against us.

C. Organizational Structure

We currently have one wholly owned significant subsidiary, Collect Biotherapeutics Ltd., which is incorporated in the State of Israel.

D. Property, Plant and Equipment

Our headquarters are currently located in Kfar Saba, Israel and originally consisted of approximately 4,360 square feet of leased office space under a lease until October 14, 2020. The monthly rental fee is NIS 26,000. In addition, we hold options to extend the lease for two additional two-year periods each. On October 24, 2017, we leased a further 258 square feet of office space under a lease until December 31, 2018, with options to extend for two additional two-year periods each. We subsequently cancelled this lease and on March 21, 2018, we leased a further 1,500 square feet of office space, for a total leased space of 5,860 square feet, until September 23, 2019 with an option to extend for a further 18 months. The monthly rental fee for the additional space is NIS 8,000. We may require additional space and facilities as our business expands.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this annual report on Form 20-F. This discussion and other parts of this annual report on Form 20-F contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under “Risk Factors” and elsewhere in this annual report on Form 20-F. We report financial information under IFRS as issued by the IASB and none of the financial statements were prepared in accordance with generally accepted accounting principles in the United States.

A. Operating Results

To date, we have not generated revenue from the sale of any product, and we do not expect to generate significant revenue within the next year at least. As of December 31, 2018, we had an accumulated deficit of NIS 84.0 million (approximately \$22.4 million). Our financing activities are described below under “Finance Expense and Income.”

Operating Expenses

Our current operating expenses consist of two components – research and development expenses, and general and administrative expenses.

Research and Development Expenses, net

Our research and development expenses consist primarily of salaries and related personnel expenses, subcontractor expenses, patent registration fees, materials, share-based payment and other related research and development expenses, net of grants.

The following table discloses the breakdown of research and development expenses:

	Year ended December 31,			
	2016	2017	2018	2018
	NIS			USD*
(in thousands)				
Payroll	3,711	5,486	6,629	1,769
Subcontractors	1,578	1,504	1,788	477
Patent registration	409	256	647	173
R&D related purchases	1,676	1,574	2,386	637
Share-based payment	253	1,940	807	215
Other expenses	629	743	1,256	334
	<u>8,256</u>	<u>11,503</u>	<u>13,513</u>	<u>3,605</u>

* USD presented as convenience translation using December 31, 2018 NIS/USD exchange rate of NIS 3.748.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, professional service fees, director fees, office expenses, taxes and fees, share-based payment and other general and administrative expenses.

The following table discloses the breakdown of general and administrative expenses:

	Year ended December 31,			
	2016	2017	2018	2018
	NIS			USD*
(in thousands)				
Payroll	2,994	3,076	5,277	1,408
Professional services	2,074	3,745	3,785	1,010
Director fees	318	354	712	190
Office expense	466	449	325	87
Share-based payment	1,299	3,444	3,730	995
Other expenses	817	1,862	1,905	508
Total	<u>7,968</u>	<u>12,930</u>	<u>15,734</u>	<u>4,198</u>

* USD presented as convenience translation using December 31, 2018 NIS/USD exchange rate of NIS 3.748.

Comparison of the year ended December 31, 2018 to the year ended December 31, 2017 to the year ended December 31, 2016

Results of Operations

	December 31,			December 31,		
	2016	2017	2018	2016*	2017*	2018*
	(in thousands of NIS)			(in thousands of USD)		
Research and development expenses, net	8,256	11,503	13,513	2,147	3,318	3,605
General and administrative expenses	7,968	12,930	15,734	2,072	3,729	4,198
Other income	(280)	-	-	(73)	-	-
Operating loss	15,944	24,433	29,247	4,146	7,047	7,803
Finance expense (income), net	(627)	3,791	(9,134)	(163)	1,094	(2,436)
Total comprehensive loss	15,317	28,224	20,113	3,983	8,141	5,367
Loss attributable to holders of Ordinary Shares	15,317	28,224	20,113	3,983	8,141	5,367

* USD presented as convenience translation using year end 2018, 2017, 2016 NIS/USD exchange rate of: NIS 3.748, NIS 3.467 and NIS 3.845, respectively.

Research and Development Expenses, net

Our research and development expenses for the year ended December 31, 2018 amounted to NIS 13.5 million (approximately \$3.6 million), representing an increase of NIS 2.0 million (approximately \$0.3 million), or 17%, compared to NIS 11.5 million (approximately \$3.3 million) for the year ended December 31, 2017. The increase was primarily attributable to an increase of NIS 2.1 million (approximately \$0.3 million) from purchasing materials and an increase in salaries and related expenses reflecting the progress in our research and development activities and the growth of our employees working on our research and development activities.

Our research and development expenses for the year ended December 31, 2017 amounted to NIS 11.5 million (approximately \$3.3 million), representing an increase of NIS 3.2 million (approximately \$1.2 million), or 39%, compared to NIS 8.3 million (approximately \$2.1 million) for the year ended December 31, 2016. The increase was primarily attributable to an increase of NIS 1.7 million (approximately \$0.5 million) from share-based payment and an increase of salaries and related personnel expenses in an amount of NIS 1.8 million (approximately \$0.5 million) reflecting the growth in our activities resulting from an increase in the number of employees engaged in research and development related activities from thirteen to eighteen.

General and Administrative Expenses

Our general and administrative expenses totaled NIS 15.7 million (approximately \$ 4.2 million) for the year ended December 31, 2018, an increase of NIS 2.8 million (approximately \$0.5 million), or 22%, compared to 12.9 million (approximately \$3.7 million) for the year ended December 31, 2017. The increase resulted primarily from an increase of NIS 2.2 million (approximately \$0.6 million) in salaries and related personnel expenses due to an increase in the number of our business development personnel.

Our general and administrative expenses totaled NIS 12.9 million (approximately \$3.7 million) for the year ended December 31, 2017, an increase of NIS 4.9 million (approximately \$1.7 million), or 61%, compared to NIS 8.0 million (approximately \$2.0 million) for the year ended December 31, 2016. The increase resulted primarily from an increase of NIS 2.2 million (approximately \$0.6 million) in share based payment, an increase of NIS 1.2 million (approximately \$0.3 million) in professional services due to increase in legal and investor and public relations expenses as the company was a Nasdaq company for the all year and an increase of NIS 1.6 million (approximately \$0.5 million) from other expenses which mainly represent the company business development activities.

Operating Loss

As a result of the foregoing, our operating loss for the year ended December 31, 2018 was NIS 29.2 million (approximately \$7.8million), as compared to operating loss of NIS 24.4 million (approximately \$7.0 million) for the year ended December 31, 2017, an increase of NIS 4.8million (approximately \$0.8 million), or 19.7%.

As a result of the foregoing, our operating loss for the year ended December 31, 2017 was NIS 24.4 million (approximately \$7.0 million), as compared to an operating loss of NIS 15.9 million (approximately \$4.1 million) for the year ended December 31, 2016, an increase of NIS 8.5 million (approximately \$2.9 million), or 53%.

Finance Expense and Income

Finance expense and income mainly consist of bank fees and other transactional costs, changes in the fair value of certain price adjustment mechanisms in warrants that were issued to investors who participated in certain fund raising rounds, and exchange rate differences.

We recognized net financial income of NIS 9.1 million (approximately \$2.4 million) for the year ended December 31, 2018, compared to net financial expenses of NIS 3.8 million (approximately \$1.1 million) for the year ended December 31, 2017. The change is primarily due to the change in the fair value of the listed warrants granted in our U.S. initial public offering, or IPO, in 2016 and to the unregistered warrants granted in our registered direct offerings in 2017 and in 2018.

We recognized net financial expenses of NIS 3.8 million (approximately \$1.1 million) for the year ended December 31, 2017, compared to net financial income of NIS 0.6 million (approximately \$0.16 million) for the year ended December 31, 2016. The change is primarily due to the change in the fair value of the listed warrants granted in the IPO in 2016 and to the unregistered warrants granted in our registered direct offering in 2017.

Total Comprehensive Loss

As a result of the foregoing, our comprehensive loss for the year ended December 31, 2018 was NIS 20.1 million (approximately \$5.4 million), as compared to NIS 28.2 million (approximately \$8.1 million) for the year ended December 31, 2017, decrease of NIS 8.1 million (approximately \$2.8 million), or 29%.

As a result of the foregoing, our comprehensive loss for the year ended December 31, 2017 was NIS 28.2 million (approximately \$8.1 million), as compared to NIS 15.3 million (approximately \$4.0 million) for the year ended December 31, 2016, an increase of NIS 12.9 million (approximately \$4.1 million), or 84%.

Critical Accounting Policies and Estimate

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with IFRS as issued by the IASB. 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 during the reporting periods. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are more fully described in Note 2 to our audited financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Share-based payment transactions

From time to time, we grant to our employees and other service providers remuneration in the form of equity-settled share-based instruments, such as options to purchase ordinary shares. The cost of equity-settled transactions with employees is measured at the fair value of the equity instruments granted at grant date. The fair value is determined using an acceptable option pricing model. As for other service providers, the cost of the transactions is measured at the fair value of the goods or services received as consideration for equity instruments. In cases where the fair value of the goods or services received as consideration of equity instruments cannot be measured, they are measured by reference to the fair value of the equity instruments granted.

The cost of equity-settled transactions is recognized in profit or loss, together with a corresponding increase in equity, during the period in which the performance or service conditions are satisfied, and ending on the date on which the relevant employees become fully entitled to the award. No expense is recognized for awards that do not ultimately vest, except for awards where vesting is conditional upon a market condition, which are treated as vested irrespective of whether the market condition is satisfied, provided that all other vesting conditions (service and/or performance) are satisfied. When we change the conditions of the award of equity-settled instruments, an additional expense is recognized beyond the original expense, calculated in respect of a change that increases the total fair value of the remuneration granted or benefits the other service provider according to the fair value on date of change. Cancellation of the award of equity-settled instruments is accounted for as having vested at the cancellation date and the expense not yet recognized in respect of the award is recognized immediately. However, if the cancelled grant is replaced by a new grant, and is intended as an alternate grant at the date awarded, the cancelled and new awards will both be accounted for as a change to the original award, as described above.

Option Valuations

The determination of the grant date fair value of options using an option pricing model (we utilize the Black-Scholes model) is affected by estimates and assumptions regarding a number of complex and subjective variables. These variables include the expected volatility of our share price over the expected term of the options, share option exercise and cancellation behaviors, risk-free interest rates and expected dividends, which are estimated as follows:

- *Volatility.* The expected share price volatility is based on the historical volatility in the trading price of our ordinary shares as well as comparable companies on the Nasdaq Capital Market and benchmarks of related companies.
- *Expected Term.* The expected term of options granted is based upon the contractual life of the options and represents the period of time that options granted are expected to be outstanding.
- *Risk-Free Rate.* The risk-free interest rate is based on the yield from Israeli government bonds with a term equivalent to the contractual life of the options.
- *Expected Dividend Yield.* We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we use an expected dividend yield of zero.

Impairment of non-financial assets

We evaluate the need to record an impairment of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable.

If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount. The recoverable amount is the higher of fair value less costs of sale and value in use. In measuring value in use, the expected future cash flows are discounted using a pre-tax discount rate that reflects the risks specific to the asset. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs. Impairment losses are recognized in profit or loss.

An impairment loss of an asset, other than goodwill, is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, shall not be increased above the lower of the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years and its recoverable amount. The reversal of impairment loss of an asset presented at cost is recognized in profit or loss.

IFRS 16, Leases

In January 2016, the IASB issued IFRS 16, "Leases". According to IFRS 16, a lease is a contract, or part of a contract, that conveys the right to use an asset for a period of time in exchange for consideration.

According to IFRS 16:

- Lessees are required to recognize an asset and a corresponding liability in the statement of financial position in respect of all leases (except in certain cases) similar to the accounting treatment of finance leases according to the existing IAS 17, "Leases".
- Lessees are required to initially recognize a lease liability for the obligation to make lease payments and a corresponding right-of-use asset. Lessees will also recognize interest and depreciation expenses separately.
- Variable lease payments that are not dependent on changes in the Consumer Price Index ("CPI") or interest rates, but are based on performance or use (such as a percentage of revenues) are recognized as an expense by the lessees as incurred and recognized as income by the lessors as earned.
- In the event of change in variable lease payments that are CPI-linked, lessees are required to remeasure the lease liability and the effect of the remeasurement is an adjustment to the carrying amount of the right-of-use asset.

- IFRS 16 includes two exceptions according to which lessees are permitted to elect to apply a method similar to the current accounting treatment for operating leases. These exceptions are leases for which the underlying asset is of low value and leases with a term of up to one year.
- The accounting treatment by lessors remains substantially unchanged, namely classification of a lease as a finance lease or an operating lease.

For leases existing at the date of transition, IFRS 16 permits lessees to use either a full retrospective approach, or a modified retrospective approach, with certain transition relief whereby restatement of comparative data is not required.

IFRS is effective for annual periods beginning on or after January 1, 2019. We have made an initial evaluation of the impact of implementing this guidance on our consolidated financial statements. Based on this, we believe that beginning in 2019, we will recognize an amount of NIS 868 as an asset and liability in our balance sheet at the date of recognition.

Financial Liabilities

Financial liabilities within the scope of IFRS 9 are initially measured at fair value. After initial recognition, other liabilities are measured according to their terms at amortized cost using the effective interest method, taking into account directly attributable transaction costs.

The warrants were classified as a financial liability at fair value measured by quoted price and are marked to market through profit or loss in accordance with IFRS 9, and after initial recognition, changes in fair value are recognized in profit or loss.

Issue of a Unit of Securities

The issue of a unit of securities involves the allocation of the proceeds received (before issue expenses) to the securities issued in the unit based on the following order: financial derivatives and other financial instruments measured at fair value in each period. Then fair value is determined for financial liabilities that are measured at amortized cost. The proceeds allocated to equity instruments are determined to be the residual amount. Issue costs are allocated to each component pro rata to the amounts determined for each component in the unit.

B. Liquidity and Capital Resources

Overview

As of December 31 2018, we had NIS 17.8 million (approximately \$4.7 million) in cash and cash equivalents and marketable securities. In February 2019, we raised NIS 22.9 million (\$6.1 million) in net proceeds in a follow-on underwritten public offering.

The table below presents our cash flows:

	Year ended December 31,					
	2016	2017	2018	2016*	2017*	2018*
	(in thousands of NIS)			(in thousands of USD)		
Net cash used in operating activities	(14,412)	(17,770)	(23,635)	(3,748)	(5,126)	(6,306)
Net cash provided by (used in) Investing activities	(18,012)	10,091	13,708	(4,684)	2,910	3,657
Net cash provided by financing activities	34,924	15,813	12,759	9,083	4,562	3,405
Net increase in cash and cash equivalents	2,366	7,455	4,075	615	2,150	1,088

* USD presented as convenience translation using year end 2018, 2017, 2016 NIS/USD exchange rate of: NIS 3.748, NIS 3.467 and NIS 3.845, respectively.

Operating Activities

Net cash used in operating activities was NIS 23.6 million (approximately \$6.3 million) for the year ended December 31, 2018, compared with net cash used in operating activities of approximately NIS 17.7 million (approximately \$5.1 million) for the year ended December 31, 2017. The increases in such periods are primarily due to increases in research and development expenses.

Net cash used in operating activities was NIS 17.7 million (approximately \$5.1 million) for the year ended December 31, 2017, compared with net cash used in operating activities of approximately NIS 14.4 million (approximately \$3.7 million) for the year ended December 31, 2016. The increases in such periods are primarily due to increases in research and development expenses.

Investing Activities

Net cash provided by investing activities of NIS 13.7 million (approximately \$3.6 million) during 2018 primarily reflects net proceeds from short-term deposits and marketable securities.

Net cash provided by investing activities of NIS 10.1 million (approximately \$2.9 million) during 2017 primarily reflects net proceeds from short-term deposits and marketable securities.

Net cash used in investing activities of NIS 18.0 million (approximately \$4.7 million) during 2016 primarily reflects increase in short-term deposits.

Financing Activities

Net cash provided by financing activities in the years ended December 31, 2018, 2017 and 2016 consisted of NIS 12.8 million (approximately \$3.4 million), NIS 15.8 million (approximately \$4.6 million), and NIS 34.9 million (approximately \$9.1 million) respectively, of net proceeds, mainly from the issuance of ordinary shares (including ordinary shares represented by ADSs) and warrants.

In March 2016, we issued an aggregate of 5,783,437 ordinary shares pursuant to a private placement, at a price of NIS 1.39 (approximately \$0.36) per share. In addition, we issued warrants to purchase up to 1,927,801 ordinary shares, which had an exercise price of NIS 2.1 (approximately \$0.54) per warrant. The warrants expired on March 7, 2018.

In August 2016, we issued an aggregate of 1,292,308 ADSs and listed warrants to purchase 1,035,121 ADSs in our IPO, at a price of \$6.50 per ADS resulting in gross proceeds of approximately \$8.4 million.

On September 11, 2017, we sold to certain accredited investors an aggregate of 531,136 ADSs in a registered direct offering at \$8.10 per ADS resulting in gross proceeds of approximately \$4.3 million. In addition, we issued to the investors unregistered warrants to purchase 265,568 ADSs in a private placement.

On January 31, 2018, we sold to certain institutional investors an aggregate of 484,848 ADSs in a registered direct offering at \$8.25 per ADS resulting in gross proceeds of approximately \$4.0 million. In addition, we issued to the investors unregistered warrants to purchase 266,667 ADSs in a private placement.

On February 12, 2019, in a follow-on underwritten public offering we sold an aggregate of 1,889,000 each consisting of (i) one ADS, and (ii) one warrant to purchase one ADS, at a public offering price of \$1.50 per unit, and (b) 2,444,800 pre-funded units, each consisting of (i) one pre-funded to purchase one ADS, and (ii) one warrant, at a public offering price of \$1.49 per Pre-funded Unit. In connection with the offering, we granted the underwriters a 45-day option to purchase up to an additional 650,070 ADSs and/or 650,070 warrants to purchase up to an additional 650,070 ADSs. The underwriters partially exercised their over-allotment option to purchase an aggregate of 350,000 additional ADS and additional warrants to purchase 650,070 ADSs. Subsequently, of the pre-funded warrants issued, we issued 2,108,000 ADSs upon exercise of pre-funded warrants.

Current Outlook

We have financed our operations to date primarily through proceeds from issuance of our ordinary shares and ordinary shares represented by ADSs and warrants. We have incurred losses and generated negative cash flows from operations since July 2013. In addition, we have an accumulated deficit of NIS 84.0 million (approximately \$22.4 million) as of December 31, 2018. We have never generated any revenue from the sale or licensing of our products and we do not expect to generate significant revenue within the next year at least.

We expect that our existing cash and cash equivalents will be sufficient to fund our current operations until the end of the first quarter of 2020. We have expended and believe that we will continue to expend significant operating and capital expenditures for the foreseeable future developing our ApoGraft technology platform and our ApoTainer collection kits. These expenditures will include, but are not limited to, costs associated with research and development, manufacturing, conducting preclinical experiments and clinical trials, contracting manufacturing organizations, hiring additional management and other personnel and obtaining regulatory approvals, as well as commercializing any products approved for sale. Furthermore, we expect to incur additional costs associated with operating as a public company in the United States. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our ApoGraft technology platform, our ApoTainer collection kits and any other future products. In addition, other unanticipated costs may arise. As a result of these and other factors currently unknown to us, we require substantial, additional funds through public or private equity or debt financings or other sources, such as strategic partnerships and alliances and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

Our future capital requirements depend on many factors, including:

- the number and characteristics of products we develop from our ApoGraft technology platform;
- the scope, progress, results and costs of researching and developing our ApoGraft technology platform and any future products, and conducting preclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- the cost of commercialization activities if any products are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing any future product we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing, supply or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs of in-licensing further patents and technologies;
- the cost of development of in-licensed technologies;
- the timing, receipt and amount of sales of, or royalties on, any future products;
- the expenses needed to attract and retain skilled personnel; and
- any product liability or other lawsuits related to any future products.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities for our ApoGraft technology platform or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our ApoGraft technology platform, our ApoTainer collection kits or any future products. These factors, among others, raise substantial doubt about our ability to continue as a going concern. Our independent auditors, in their report on our audited financial statements for the year ended December 31, 2018 expressed substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if we were unable to continue as a going concern.

C. Research and Development, Patents and Licenses

See above, under “Item 5. Operating and Financial Review and Prospects—A. Operating Results.”

D. Trend Information

We are a development stage company and it is not possible for us to predict with any degree of accuracy the outcome of our research, development or commercialization efforts. As such, it is not possible for us to predict with any degree of accuracy any significant trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net sales or revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause financial information to not necessarily be indicative of future operating results or financial condition. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are in this “Operating and Financial Review and Prospects.”

E. Off-Balance Sheet Arrangements

We participated in programs sponsored by the BIRD Foundation for the support of research and development activities. We are obligated to pay royalties to the BIRD Foundation, amounting to 5% of the gross sales of the products and other related revenues developed from such activities, up to an amount of 150% from the grant received from the BIRD Foundation by us indexed to the U.S. consumer price index.

As of December 31, 2018, we received an aggregate grant of \$120,000 from the BIRD Foundation in support of the development and commercialization of our stem cell selection technology in collaboration with Entegris. We are no longer pursuing our collaboration with Entegris under a previously entered into Joint Product Development Agreement.

F. Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2018:

	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
			(in thousands)		
Operating Lease Obligations in NIS	1,337	729	608	-	-
Operating Lease Obligations in \$	357	195	162	-	-

The operating lease obligations in the foregoing table include our commitments under the lease agreements for our facility in Kfar Saba. See “Item 4. Information on the Company—D. Property, Plant and Equipment.”

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

Directors and Senior Management

We are managed by a board of directors, which is currently comprised of eight members, and our senior management. Each of our members of senior management is appointed by our board of directors. The table below sets forth our directors and senior management. The business address for each of our directors and senior management is c/o Collect Biotechnology Ltd. 23 Hata’as Street, Kfar Saba, Israel 44425.

Name	Age	Position
Kasbian Nuriel Chirich	60	Chairman of the Board of Directors
Dr. Shai Yarkoni	60	Chief Executive Officer and Director
Eyal Leibovitz	57	Chief Financial Officer
Dr. Ronit Bakimer-Kleiner	57	Chief Development Officer
Andrew Sabatier ⁽⁴⁾	51	Chief Business Officer
Dr. Amos Ofer	43	Vice President of Operations
Dr. Yael Kenan	56	Vice President of Clinical Affairs
Smadar Har Tuv	46	Quality Assurance Director
Abraham Nahmias ⁽¹⁾⁽²⁾⁽³⁾	63	Director
Dr. Ruth Ben Yakar	49	Director
Michael Berelowitz ⁽¹⁾	74	Director
Ruhama Avraham ⁽¹⁾⁽²⁾⁽³⁾	55	External Director
David Braun ⁽¹⁾	47	Director
Jonathan Burgin ⁽¹⁾⁽²⁾⁽³⁾	57	External Director

(1) Indicates independent director under the Nasdaq Capital Market rules.

(2) Member of our Audit Committee.

(3) Member of our Compensation Committee.

(4) On March 14, 2019, we gave notice of termination to Mr. Sabatier. His last day of employment is yet to be determined.

Kasbian Nuriel Chirich co-founded our subsidiary, Collect Biotherapeutics, in 2011 and has served as Chairman of our board of directors since 2013 and of our subsidiary since inception. Mr. Chirich is an entrepreneur and businessman with extensive financial and business expertise with innovative ventures throughout East Africa and Israel. Mr. Chirich is a real estate developer and was previously the founder and general manager of Leadcom Kasbian, which is credited, among other things, with establishing the national television of Tanzania and building the infrastructure of two cellular networks in Tanzania. Mr. Chirich serves as the Honorary Consul of Tanzania in Israel.

Dr. Shai Yarkoni co-founded our subsidiary, Collect Biotherapeutics, in 2011, and has served as our Chief Executive Officer and a director since 2013 and of our subsidiary since inception. Dr. Yarkoni has over 15 years of clinical and management experience in the biopharmaceutical industry. Dr. Yarkoni is a founder of Sne, an Israeli technology transfer company established in 2013. Since 1999, Dr. Yarkoni has also been the Chief Executive Officer and Chairman of GASR Biotechnology, a life sciences consulting and investing firm. From 2009 until 2013, Dr. Yarkoni served as Chief Executive Officer of BioNegev, an international innovation center for biotechnology and life sciences in the Negev region. Prior to that he served as Chief Executive Officer of Target-In Ltd., a developer of therapeutic recombinant proteins for cancer treatment and as Chief Technology Officer and Vice President R&D of Collgard Biopharmaceutical, a tissue therapeutics company, and was an attending OB/GYN specialist practicing for approximately thirteen years. Dr. Yarkoni holds an M.D and Ph.D from the Hadassah Medical School, Jerusalem, Israel, and is a board certified OB/GYN. Dr. Yarkoni is the author of over 60 scientific papers and inventor of approximately 20 patents.

Eyal Leibovitz has served as our Chief Financial Officer since January 1, 2017. Mr. Leibovitz has over over 27 years of experience in senior management, finance, investor relations, mergers and acquisitions business development in international pharma and biotech companies. From September 2007 to October 2011, Mr. Leibovitz served as Chief Financial Officer of Kamada Ltd. (Nasdaq:KMDA), from November 2011 to December 2015 as the Chief Financial Officer of N-trig Ltd and as Chief Financial Officer of Evogene Ltd. (NYSE:EVGN) from December 2015 to December 2016. Among his achievements, he led Kamada Ltd. to a successful large scale fund raising (including PIPE round, public rights offering, venture lending and public convertible debt) and led the sale of N-trig Ltd to Microsoft. Mr. Leibovitz hold a BBA degree from the City University of New York.

Dr. Ronit Bakimer-Kleiner has served as our Chief Development Officer since November 2017. Prior to joining us, from 2008 to 2017, Dr. Bakimer-Kleiner served as General Manager of Cognate Bioservices Israel, a contract bioservices organization focused on the regenerative medicine and cell therapy market. Prior to that from 2006 to 2008, Dr. Bakimer-Kleiner was Laboratory Director at the International Center for Cell Therapy & Cancer at Tel Aviv Sourasky Medical Center and from 1997 to 2006 held various positions at Proneuron Biotechnologies including Director of Cell Therapy. Dr. Bakimer-Kleiner holds a B.Sc. in Life Sciences from Tel Aviv University and a M.Sc. and Ph.D. in Immunology from Ben-Gurion University followed by 4 years post-doc at The Weizmann Institute of Science.

Andrew Sabatier has served as our Chief Business Officer since May 2018. Mr. Sabatier has over 20 years of experience in the biotechnology and life sciences market. Most recently, from March 2017 to May 2018, he was GE Healthcare's Sales and Market Development Leader for the United States and Canada, leading sales for GE Cell Therapy. From 2015 to 2017, Mr. Sabatier served as the Vice President of Sales of BIOSAFE America which was acquired by GE Healthcare, and from 2012 to 2015 served as the Director of Sales of BIOSAFE. Among his achievements, Mr. Sabatier was responsible for creating the cell processing market, which became the largest market for BIOSAFE, and is currently the cornerstone of GE Healthcare's cell therapy business. He has managed U.S. commercial operations and built, trained and developed international sales teams across Asia, South America, Europe, Canada, and the United States. Prior to joining BIOSAFE, Mr. Sabatier served in sales roles with Independent Health Care Consulting, Gambro, Genzyme, Cook Medical and Toshiba. Mr. Sabatier holds a B.A. in international relations from Boston University.

Dr. Amos Ofer has served as our Vice President of Operations since June 2018. Prior to joining us, since 2014, Dr. Ofer has been providing business consulting and project management services to companies in the biotechnology and pharmaceutical industries. From August 2016 to January 2018, Dr. Ofer served as the Chief Operating Officer of Valin Technologies Ltd., a biotechnology company focused on the research and development of innovative biological therapeutics and biosimilars. During this same time, Dr. Ofer served as the General Manager of Pam-Bio Ltd., a biotechnology company focused on developing a drug therapy for the treatment of hemorrhagic stroke. Prior to that, Dr. Ofer served as the Chief Executive Officer of Pam-Bio Ltd., from 2015 to 2016. He also served as the Research Director of the Gastroenterology Institute of the Tel Aviv Medical Center, which is the largest department of its kind in Israel. Dr. Ofer holds a B.Sc. in biology and a M.Sc. and Ph.D. in microbiology from Tel Aviv University and an MBA following his completion of the executive MBA program at Tel Aviv University's Recanati Business School.

Dr. Yael Kenan has served as our Vice President of Clinical Affairs since 2016. Dr. Kenan is an executive in the biotechnology, pharmaceutical and medical device industries with almost 20 years of experience in drug development and clinical, medical, and regulatory affairs. Dr. Kenan was formerly Chief Executive Officer of Lacrima Medical, Ltd., from 2013 to 2016, where she established and managed a medical device startup company that develops innovative medical device for CNS indication. Previously she served as the Chief Operating Officer of TransPharma Medical, Ltd and as Associate Director and Head of Global Clinical Drug Development for Parkinson's Disease and Clinical Trials Manager at Teva Pharmaceuticals Industries Ltd. Dr. Kenan holds a Ph.D. in biochemistry from the Hebrew University of Jerusalem followed by 4 years post-doc at NIH as a visiting fellow. She also holds an MBA in finance and marketing from The Technion – Israel Institute of Technology.

Smadar Har Tuv has served as our Quality Assurance Director since 2015. Prior to joining us, from 2012 to 2015, Ms. Har Tuv served as the Quality Assurance Manager of Macrocare Ltd. Prior to that for over 10 years, she served in quality assurance and compliance roles at Teva Pharmaceuticals Industries Ltd, including serving as the Regulatory Compliance Manager, Production Section Manager and Quality Assurance Section Manager. Ms. Har Tuv also has experience serving as an Inspector for the National Food Services of the Israeli Ministry of Health. She holds a B.Sc. in food engineering and biotechnology from The Technion – Israel Institute of Technology.

Abraham Nahmias has served as a member of our board of directors since July 2014. Since 1985, Mr. Nahmias has served as a founding partner of Nahmias-Grinberg C.P.A., an accounting firm. Mr. Nahmias serves or has served as a member of the board of directors of several private and public companies including Rotshtein Real Estate (TASE: ROTS), Orad Ltd., Allium Medical Ltd. (TASE: ALMD), Nano Dimension Ltd. (Nasdaq: NNDM) and Eviation Aircraft Ltd. (OTC: EVTNF). Mr. Nahmias holds a B.A. degree in Economics and Accounting from Tel Aviv University, and has had a C.P.A. license since 1982.

Dr. Ruth Ben Yakar has served as a member of our board of directors since July 2014. Dr. Ben Yakar has over 25 years of experience in the biomedical field, including 18 years of management in the biotech industry, leading diverse corporate, business, operational, financial, clinical development, and research activities. Since December 2014, Dr. Ben Yakar has served as the CEO and a director at BioSight Ltd., a clinical-phase biotech company and on the board of directors of Biondvax (Nasdaq: BVXV) since 2016 and Maayan Venture since 2018, and she is also a business consultant to several biomed companies, and a guest lecturer at Lahav, the Recannati Business School of Tel-Aviv University. From 2012 until 2014, Dr. Ben Yakar served as the CEO of Procognia, a biotech company traded on the TASE and from November 2014 to April 2017 she was a director at SHL Medicine (SIX Swiss Exchange: SHLTN). Additionally, from 2012 until 2015, Dr. Ben Yakar was a director at Israel Advanced Technology Industries or IATI. Prior to that, Dr. Ben Yakar served as the CEO of Thrombotech, where she led a multi-center phase II clinical trial and led the company to acquisition. She also served as the Chief Business Officer of YEDA, the technology transfer company of the Weizmann Institute of Science, responsible for the commercialization of the WIS technologies, and was Vice President in several biotech companies where she led diverse product development activities and clinical and pre-clinical R&D projects. Dr. Ben Yakar holds a PhD Cum Laude from the Weizmann Institute of Science. Her research, in the field of oncology, yielded several prestigious publications and awards.

Michael Berelowitz has served as a member of our board of directors since April 2017. Since 2011, Dr. Berelowitz has been self-employed as a biopharmaceutical consultant. From 2009 to 2011, Dr. Berelowitz served as Senior Vice President and Head of Clinical Development and Medical Affairs in the Specialty Care Business Unit at Pfizer, Inc. From 1996 to 2009, he served in various other roles at Pfizer, Inc., beginning as a Medical Director in the Diabetes Clinical Research team and then assuming positions of increasing responsibility. Prior to 1996, Dr. Berelowitz spent a number of years in academia. Dr. Berelowitz also serves on the board of directors of Recro Pharma Inc. (Nasdaq: REPH), a clinical stage specialty pharmaceutical company, Kamada Ltd. (Nasdaq: KMDA), a plasma-derived protein therapeutics company focused on orphan indications, and previously served as a director of Oramed Pharmaceuticals Inc. from June 2010 until August 30, 2016. Among his public activities, Dr. Berelowitz has served on the board of directors of the American Diabetes Association, the Clinical Initiatives Committee of the Endocrine Society, and has chaired the Task Force on Research of the New York State Council on Diabetes. He has also served on several editorial boards, including the Journal of Clinical Endocrinology and Metabolism and Endocrinology, Reviews in Endocrine and Metabolic Disorders and Clinical Diabetes. Dr. Berelowitz has authored and co-authored more than 100 peer-reviewed journal articles and book chapters in the areas of pituitary growth hormone regulation, diabetes and metabolic disorders. Dr. Berelowitz holds adjunct appointments as Professor of Medicine in the Divisions of Endocrinology and Metabolism at SUNY - Stony Brook and Mt. Sinai School of Medicine in New York.

Ruhama Avraham, has served as a member of our board of directors since December 2017. Ms. Avraham is a former member of the Knesset with a distinguished political career. Since 2013, Ms. Avraham has been providing strategic support and consulting to enterprises and organizations such as Manufacturers Association of Israel, Bank Hapoalim, Giza Singer Even Ltd., Coca Cola and Skylock, Nefesh B'nefesh and World ORT. Since 2017, Ms. Avraham serves as external director of Minrav Holdings Ltd. and Canada's Sky Line and was previously an external director of B. Yair Building Corp. Prior to that after her election to the Knesset, from 2003 to 2013, Ms. Avraham served in various political and governmental roles in Israel including Minister of Tourism, Acting Minister of the Interior, Deputy Knesset Speaker and Member of Knesset as the Opposition Chairwoman, Member of the Financial Committee and Member of the Foreign Affairs and Defense Committee. She received her bachelor's degree in social science from Bar-Ilan University, and an MBA in Organizational Management and HR Management from the Peres Academic Center.

David Braun has served as a member of our board of directors since December 2017. Mr. Braun has nearly 20 years of experience spanning across various roles in research and development, operations, business management, merger and acquisition integrations and organizational transformation. Since 2015, Mr. Braun has been the Head of Medical Device Business at Merck KGaA Group. From 2011 to 2015, Mr. Braun was Director of Global Research and Development and Operations at Newell Brands. Prior to that from 2007 to 2011, he was the Vice President in Research and Development and Operations at Biosafe. Mr. Braun has also held various positions in project management and system engineering. He received his Master of Science in applied physics and electro-optical engineering in 1997 at the National High School of Physics of Strasbourg, and has participated in Executive leadership and general management programs at IMD and at the Harvard Business School.

Jonathan Burgin has served as a member of our board of directors since October 2018. Mr. Burgin has served as the Chief Financial Officer of Anchiano Therapeutics Ltd. (TASE: ANCN) (formerly BioCancell Ltd.) between June 2011 and June 2012, was Anchiano's Chief Executive Officer from June 2012 through October 2016, and has served as Anchiano's Chief Financial Officer and Chief Operating Officer since October 2016. Mr. Burgin was Chief Financial Officer of Radcom Ltd. (Nasdaq: RDCM), a service assurance provider, from 2006 to 2011, and was Chief Financial Officer of XTL Biopharmaceuticals Ltd. (TASE: XTL, Nasdaq: XTLB), a drug development company, from 1999 to 2006. Between 1997 and 1999, he was Chief Financial Officer of YLR Capital Markets Ltd., a publicly-traded Israeli investment bank, and rose to become a Senior Manager at Kesselman & Kesselman, CPA (Israel), the Israeli member of PricewaterhouseCoopers International, Ltd., between 1984 and 1997. Mr. Burgin earned an M.B.A. and a B.A. in accounting and economics from Tel Aviv University and is certified in Israel as a Certified Public Accountant.

Our Scientific Advisory Team

Our Scientific Advisory Team includes specialists and experts in Israel, with experience in the fields of biochemistry, infectious diseases and medical research. Our Scientific Advisory Team plays an active role in advising us with respect to our products, technology development, clinical trials and safety. Our Scientific Advisory Team members are entitled, according to their work and contribution to us, to either hourly or monthly consulting fees.

Our Scientific Advisory Team is comprised of the following members:

Professor Dov Zipori is the Director of the Helen and Martin Kimmel Institute for Stem Cell Research at the WIS. Pluristem's technology is based on Prof. Zipori's scientific research.

Dr. Susan Alpert has served as the Director of Medical Device Assessment in the FDA, as well as senior VP Regulatory at Medtronic Inc. (NYSE:MDT) and C. R. BARD Inc.

Professor Robert Negrin is the Medical Director of the Clinical Bone Marrow Transplantation Laboratory and the Division Chief of the Blood and Marrow Transplant Program at Stanford University.

Professor John F. DiPersio is Chief of Oncology at the Washington University School of Medicine in St. Louis. He specializes in bone marrow transplantations, leukemia, gene therapy and GvHD.

Professor Francesco Dazzi is a specialist in Regenerative and Haematological Medicine and is KHP Lead for Cellular Therapies at King's College London. Professor Dazzi is also a member of editorial boards at leading scientific journals.

Professor Corey Cutler is a hematologist affiliated with the Dana-Farber Cancer Institute and the Brigham and Women's Hospital. He is also Associate Professor, Medicine at Harvard Medical School.

Family Relationships

There are no family relationships between any members of our executive management and our directors.

Arrangements for Election of Directors and Members of Management

There are no arrangements or understandings with major shareholders, customers, suppliers or others pursuant to which any of our executive management or our directors were selected.

B. Compensation

The aggregate compensation expensed, including share-based compensation and other compensation expensed by us and our subsidiaries to our office holders with respect to the year ended December 31, 2018 was approximately \$2.6 million.

The term 'office holder' as defined in the Companies Law includes a general manager, chief business manager, deputy general manager, vice general manager, any other person fulfilling or assuming the responsibilities of any of the foregoing positions without regard to such person's title, as well as a director, or a manager directly subordinate to the general manager or the chief executive officer. As of March 12, 2018, in addition to the eight members of the board of directors (including the Company's Chairman and Chief Executive Officer), the Company considers six other individuals, including its Chief Financial Officer, Chief Development Officer, Chief Business Officer, Vice President of Operations, Vice President of Clinical Affairs and Quality Assurance Director to be office holders.

The table below sets forth the compensation paid to our five most highly compensated senior office holders during or with respect to the year ended December 31, 2018, in the disclosure format of Regulation 21 of the Israeli Securities Regulations (Periodic and Immediate Reports), 1970. We refer to the five individuals for whom disclosure is provided herein as our “Covered Executives.”

For purposes of the table and the summary below, and in accordance with the above mentioned securities regulations, “compensation” includes base salary, bonuses, equity-based compensation, retirement or termination payments, benefits and perquisites such as car, phone and social benefits and any undertaking to provide such compensation.

Name and Principal Position	Base Salary (NIS in thousands) (including social allowance)	Variable Compensation⁽¹⁾ (NIS in thousands)	Equity-Based Compensation⁽²⁾ (NIS in thousands)	Other (NIS in thousands)	Total⁽³⁾ (NIS in thousands)	Convenience translation into USD in thousands⁽⁴⁾
Kasbian Nuriel Chirich, Chairman of the Board of Directors	643	126	957	14	1,740	464
Dr. Shai Yarkoni, Chief Executive Officer & Director	1,160	309	1,356	8	2,833	756
Eyal Leibovitz, Chief Financial Officer	922	187	505	21	1,635	436
Dr. Yael Kenan, Vice President of Clinical Affairs	678	16	52	3	749	200
Dr. Ronit Bakimer-Kleiner Chief Development Officer	628	23	46	8	705	188

(1) Amounts reported in this column refer to variable compensation such as commission, incentive and bonus payments for the year ended December 31, 2018 (including any cash bonuses paid in 2019). Cash bonuses are intended to promote our work plan and business strategy by rewarding senior office holders for achievement of business and financial goals through team work and collaboration. Key performance indicators which are factored into cash bonus determinations are individual specific and may include: (i) progress in our ongoing Phase I/II clinical trial, (ii) completion of a strategic transaction, (iii) submission of an IND, (iv) raising funds, (v) FasL production of first clinical batch, and (vi) establishment of U.S. subsidiary.

(2) Amounts reported in this column represent the expense recorded in the Company’s financial statements for the year ended December 31, 2018 with respect to equity-based compensation. Assumptions and key variables used in the calculation of such amounts are discussed in note 12 to the consolidated financial statements.

(3) All amounts reported in the table are in terms of cost to us.

(4) Calculated using the exchange rate reported by the Bank of Israel for December 31, 2018 at the rate of one U.S. dollar per NIS 3.748.

Compensation of Directors

As approved by our shareholders at our 2018 annual meeting of shareholders, in connection with their services as directors of the Company and in accordance with the companies regulations (rules regarding compensation and expenses to external directors – 2000), each of our directors (other than Dr. Yarkoni and Mr. Chirich) from time to time, including external directors, is entitled to an annual payment of NIS 34,200, plus value-added tax, or VAT, if applicable, payable quarterly at the end of each quarter. In addition, each of our non-employee directors are entitled to receive an average payment of NIS 1,090 plus VAT, if applicable, per each board meeting or board committee meetings they have participated in.

For the outstanding equity-based awards granted to our directors, see below under “Item 6. Directors, Senior Management and Employees—E. Share Ownership—Certain Information Concerning Equity Awards to Office Holders.”

Compensation of External Directors

Each of our external directors is entitled to an annual amount of NIS 34,200, plus VAT, if applicable, payable in quarterly installments at the end of each quarter. In addition, in accordance with the companies regulations (rules regarding compensation and expenses to external directors – 2000), each of our external directors are entitled to receive an average payment of NIS 1,090 plus VAT, if applicable, per each board meeting or board committee meetings they have participated in. The compensation of external directors is also subject to the provisions of the Israeli regulations promulgated pursuant to the Companies Law governing the terms of compensation payable to external directors, or the Compensation Regulations, which provide that such compensation will not be less than the Minimum Amount (as such term is defined in the Compensation Regulations). See also “Item 6. Directors, Senior Management and Employees—C. Board Practices—External Directors & Financial Experts” below.

Employment Agreements with Senior Management

Our senior management are employed under the terms and conditions prescribed in personal contracts. These personal contracts provide for notice periods of varying duration for termination of the agreement by us or by the relevant member of senior management, during which time such person will continue to receive base salary and benefits. These agreements also contain customary provisions regarding non-competition, confidentiality of information and assignment of inventions. However, the enforceability of the non-competition and assignment of inventions provisions may be limited under applicable law. See “Risk Factors — Risks Related to Our Operations in Israel.”

For a description of the terms of our options and option plans, see “Item 6. Directors, Senior Management and Employees—E. Share Ownership” below.

Chairman of the Board of Directors Agreement with Kasbian Nuriel Chirich

On April 30, 2013, we entered into a Chairman of the board of directors agreement with Kasbian Nuriel Chirich, employing him on a part-time basis as Chairman of the board of directors. Mr. Chirich’s terms of employment have been subsequently amended on July 24, 2016 and July 5, 2018. Mr. Chirich’s current monthly salary is NIS 42,000 and he is entitled to a maximum bonus of up to six monthly salaries. Mr. Chirich is also entitled to reimbursement for reasonable out-of-pocket expenses, including travel expenses, and an allocation to a manager’s insurance policy, pension plan, study fund and disability insurance. The agreement originally had a term of 36 months and was renewable for additional terms of 36 months subject to any approvals that are required by law. The current term terminates on June 30, 2019. The agreement is terminable by either party upon 180 days prior written notice and is terminable immediately by Celect Biotherapeutics for cause as such term is defined in the employment agreement.

On August 26, 2015, we granted options to purchase 72,000 ordinary shares to Mr. Chirich. The options are exercisable at NIS 1.90 per share and expire on August 26, 2025. The options vest each quarter from the date of grant over three years in twelve equal installments.

On February 28, 2017, we granted options to purchase 1,442,729 ordinary shares to Mr. Chirich. The options are exercisable at NIS 1.20 per share and expire on February 27, 2027. The options vest over a period of 48 months, with one quarter vesting 12 months from the grant date and the remaining three quarters vesting over the remaining 36 months on a quarterly basis beginning 12 months from the grant date.

On July 5, 2018, we granted options to purchase 632,710 ordinary shares to Mr. Chirich. The options are exercisable at NIS 1.515 per share and expire on July 4, 2028. The options vest over a period of 48 months, with one quarter vesting on March 12, 2019 and the remaining three quarters vesting over the remaining 36 months on a quarterly basis beginning March 12, 2019.

Employment Agreement with Shai Yarkoni

On April 30, 2013, we entered into an employment agreement with Dr. Shai Yarkoni employing him on full-time basis as Chief Executive Officer. Dr. Yarkoni’s terms of employment have been subsequently amended on July 24, 2016. Dr. Yarkoni’s current monthly salary is NIS 70,000 and he is entitled to a maximum bonus of up to six monthly salaries. Dr. Yarkoni is entitled to an allocation to a manager’s insurance policy and study fund. Dr. Yarkoni is also entitled to reimbursement for reasonable out-of-pocket expenses, including travel expenses and a company car and mobile phone. The agreement originally had a term of 36 months and was extended for a further 36 months. The current term terminates on June 30, 2019. The agreement is terminable by either party upon 180 days prior written notice and terminable immediately by us for cause as such term is defined in the employment agreement.

On September 8, 2014, we granted options to purchase 1,200,000 ordinary shares to Dr. Yarkoni. The options are exercisable at a price of NIS 1.40 per share. The options vested each quarter from the date of grant over three years in twelve equal installments and are fully vested. The options expire on September 8, 2024.

On August 26, 2015, we granted options to purchase 72,000 ordinary shares to Dr. Yarkoni. The options are exercisable at NIS 1.90 per share and expire on August 26, 2025. The options vest each quarter from the date of grant over three years in twelve equal installments.

On February 28, 2017, we granted options to purchase 3,024,040 ordinary shares to Dr. Yarkoni for his service on the board of directors. The options are exercisable at NIS 1.20 per share and expire on February 27, 2027. The options vest over a period of 48 months, with one quarter vesting 12 months from the grant date and the remaining three quarters vesting over the remaining 36 months on a quarterly basis beginning 12 months from the grant date.

Employment Agreement with Eyal Leibovitz

On October 25, 2016, we entered into an employment agreement with Eyal Leibovitz, employing him on full-time basis as Chief Financial Officer effective December 31, 2016. Mr. Leibovitz's current monthly salary is NIS 52,500. In addition, Mr. Leibovitz will be entitled to an annual bonus equal up to 5 months' salary based upon the completion of certain targets to be determined by the compensation committee and the board of directors, commencing in 2017 and thereafter. Mr. Leibovitz is entitled to an allocation to a manager's insurance policy and study fund. Mr. Leibovitz is also entitled to reimbursement for reasonable out-of-pocket expenses, including travel expenses, professional fees, director and officer insurance and a company car and mobile phone. The agreement is terminable by either party upon 90 days prior written notice and terminable immediately by us for cause as such term is defined in the employment agreement.

In addition, pursuant to the employment agreement, we granted to Mr. Leibovitz options to purchase 1,936,503 ordinary shares at an exercise price of NIS 0.819 per share. The options vest on a quarterly basis in equal installments over 36 months. In the case of termination of the employment agreement not due to a material breach as defined therein, the vested options shall be exercisable for a period of 12 months from the date of termination. In addition, the employment agreement provided that upon the earlier of one year from the date of the option grant or such time as an analyst from a reputable investment bank in the U.S. publishes a favorable analyst report, Mr. Leibovitz will be entitled to an additional option to purchase 107,584 ordinary shares. These options were granted on January 1, 2018.

Services Agreement with Dr. Ruth Ben Yakar

In September 2014, a special meeting of shareholders approved entering into a services agreement with Dr. Ruth Ben Yakar under which Dr. Ben Yakar will provide up to 20 hours per month of assistance to our Chief Executive Officer in business development and raising money for a monthly fee of NIS 6,000. In April 2015, our shareholders approved an increase to Dr. Ben Yakar's monthly fee to up to NIS 14,000, reflecting a maximum of 40 hours per month of services, effective November 15, 2014. During 2018, Dr. Ben Yakar did not provide any consulting services to us.

In addition, in September 2014, we granted to Dr. Ben Yakar options to purchase 100,000 ordinary shares at an exercise price of NIS 1.40 per share. The options vested on a quarterly basis in equal installments over 36 months and are fully vested. The options expire on September 28, 2025.

On August 26, 2015, we granted options to purchase 72,000 ordinary shares to Dr. Ben Yakar. The options are exercisable at NIS 1.90 per share and expire on August 26, 2025. The options vest each quarter from the date of grant over three years in twelve equal installments.

On February 28, 2017, we granted options to purchase 78,000 ordinary shares to Dr. Ben Yakar. The options are exercisable at NIS 1.20 per share and expire on February 27, 2027. The options vest over a period of 48 months, with one quarter vesting 12 months from the grant date and the remaining three quarters vesting over the remaining 36 months on a quarterly basis beginning 12 months from the grant date.

C. Board Practices

Introduction

Board of Directors

Under the Companies Law and our articles of association, our board of directors directs our policy and supervises the performance of our Chief Executive Officer. 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. All other executive officers are also appointed by our board of directors, and are subject to the terms of any applicable employment or services agreements that we may enter into with them or with certain entities through which we receive their services.

All of our directors other than Dr. Shai Yarkoni, Kasbian Nuriel Chirich and Dr. Ruth Ben Yakar are independent under the Nasdaq Capital Market rules. The definition of independent director under the Nasdaq Capital Market rules and external director under the Companies Law overlap to a significant degree such that we would generally expect the two directors serving as external directors to satisfy the requirements to be independent under the Nasdaq Capital Market rules. The definition of external director includes a set of statutory criteria that must be satisfied, including criteria whose aim is to ensure that there is no factor which would impair the ability of the external director to exercise independent judgment. The definition of independent director specifies similar, if slightly less stringent, requirements in addition to the requirement that the board of directors consider any factor which would impair the ability of the independent director to exercise independent judgment. In addition, our external directors each serve for a period of three years. However, external directors must be elected by a special majority of shareholders, while independent directors may be elected by an ordinary majority. See "— External Directors" below for a description of the requirements under the Companies Law for a director to serve as an external director.

Under our articles of association, our board of directors must consist of at least five and not more than twelve directors, including at least two external directors required to be appointed under the Companies Law. Our board of directors currently consists of eight members.

Under a founders agreement among Kasbian Nuriel Chirich, our Chairman, Dr. Shai Yarkoni, our Chief Executive Officer and director, and Dr. Nadir Askenasy, our former Chief Technology Officer, each founder holding at least 30% of our share capital shall be entitled to recommend the appointment of one director (and remove any director so appointed). In addition, under a voting agreement among Kasbian Nuriel Chirich and Dr. Shai Yarkoni, the parties agreed to coordinate their votes with respect to any vote taken of our shareholders. See “Related Party Transactions” below. We are not a party to this founders agreement or voting agreement and are not bound by it. Other than our two external directors, our directors are elected by an ordinary resolution at the annual and/or special general meeting of our shareholders. Because our ordinary shares do not have cumulative voting rights in the election of directors, 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. See “— External Directors” below. We have held elections for each of our non-external directors at each annual meeting of our shareholders since our initial public offering in Israel.

In addition, our articles of association allow our board of directors to appoint directors to fill vacancies on our board of directors, for a term of office ending on the earlier of the next annual general meeting of our shareholders, or the conclusion of the term of office in accordance with our articles of association or any applicable law, subject to the maximum number of directors allowed under the articles of association. External directors are elected for an initial term of three years and may be elected for up to two additional three-year terms, provided that, for Israeli companies traded on the Nasdaq Capital Market and certain other international exchanges, such term may be extended indefinitely in increments of additional three-year terms. External directors may be removed from office only under the limited circumstances set forth in the Companies Law. See “— External Directors” below.

Under the Companies Law, our board of directors must determine the minimum number of directors who are required to have accounting and financial expertise. See “— External Directors.” In determining the number of directors required to have such expertise, our board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that the minimum number of directors of our company who are required to have accounting and financial expertise is two. Our board of directors has determined that Jonathan Burgin and Abraham Nahmias have accounting and financial expertise and possess professional qualifications as required under the Companies Law.

Chairman of the Board

Our articles of association provide that the Chairman of the board of directors is appointed by the members of the board of directors and serves as Chairman of the board of directors throughout his term as a director, unless resolved otherwise by the board of directors. Under the Companies Law, the Chief Executive Officer or a relative of the Chief Executive Officer may not serve as the Chairman of the board of directors, and the Chairman or a relative of the Chairman may not be vested with authorities of the Chief Executive Officer without shareholder approval consisting of a majority vote of the shares present and voting at a shareholders meeting, provided that either:

- 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 appointment, present and voting at such meeting (not including abstaining shareholders); or
- the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in such appointment voting against such appointment does not exceed 2% of the aggregate voting rights in the company.

In addition, a person subordinated, directly or indirectly, to the Chief Executive Officer may not serve as the Chairman of the board of directors; the Chairman of the board of directors may not be vested with authorities that are granted to those subordinated to the Chief Executive Officer; and the Chairman of the board of directors may not serve in any other position in the company or a controlled company, except as a director or Chairman of a controlled company.

External Directors

Under the Companies Law, an Israeli company whose shares have been offered to the public or whose shares are listed for trading on a stock exchange in or outside of Israel is required to appoint at least two external directors to serve on its board of directors. External directors must meet stringent standards of independence.

According to regulations promulgated under the Companies law, at least one of the external directors is required to have “financial and accounting expertise,” unless another member of the audit committee, who is an independent director under the Nasdaq Capital Market rules, has “financial and accounting expertise,” and the other external director or directors are required to have “professional expertise”. An external director may not be appointed to an additional term unless: (1) such director has “accounting and financial expertise;” or (2) he or she has “professional expertise,” and on the date of appointment for another term there is another external director who has “accounting and financial expertise” and the number of “accounting and financial experts” on the board of directors is at least equal to the minimum number determined appropriate by the board of directors.

A director has “professional expertise” if he or she holds an academic degree in certain fields or has at least five years of experience in certain senior positions.

Ruhama Avraham and Jonathan Burgin have served as our external directors since 2017 and 2018 respectively, and both have the requisite accounting and financial expertise. Ruhama Avraham was elected to serve from December 13, 2017 to December 12, 2020. Jonathan Burgin was elected to serve from October 25, 2018 to October 24, 2021.

The provisions of the Companies Law set forth special approval requirements for the election of external directors. External directors must be elected by a majority vote of the shares present and voting at a shareholders meeting, provided that either:

- such majority includes at least a majority of the shares held by all shareholders who are non-controlling shareholders and do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding abstentions, to which we refer as a disinterested majority; or
- the total number of shares voted by non-controlling shareholders and by shareholders who do not have a personal interest in the election of the external director, against the election of the external director, does not exceed 2% of the aggregate voting rights in the company.

The term controlling shareholder is defined in the Companies Law as a shareholder with the ability to direct the activities of the company, excluding such ability deriving solely from his or her position as a director of the company or from any other position with the company. 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. With respect to certain matters, a controlling shareholder is deemed to include a shareholder that holds 25% or more of the voting rights in a public company if no other shareholder holds more than 50% of the voting rights in the company.

The initial term of an external director is three years. Thereafter, an external director may be reelected by shareholders to serve in that capacity for up to two additional three-year terms, except as provided below, provided that either:

- his or her service for each such additional term is recommended by one or more shareholders holding at least 1% of the company’s voting rights and is approved at a shareholders meeting by a disinterested majority, where the total number of shares held by non-controlling, disinterested shareholders voting for such reelection exceeds 2% of the aggregate voting rights in the company. In such event, the external director so reappointed may not be a Related or Competing Shareholder, as defined below, or a relative of such shareholder, at the time of the appointment, and is not and has not had any affiliation with a Related or Competing Shareholder, at such time or during the two years preceding such person’s reappointment to serve an additional term as external director. The term “Related or Competing Shareholder” means a shareholder proposing the reappointment or a shareholder holding 5% or more of the outstanding shares or voting rights of the company, provided, that at the time of the reappointment, such shareholder, the controlling shareholder of such shareholder, or a company controlled by such shareholder, have a business relationship with the company or are competitors of the company. Additionally, the Israeli Minister of Justice, in consultation with the Israel Securities Authority, or the ISA, may determine matters that under certain conditions will not constitute a business relationship or competition with the company; or
- his or her service for each such additional term is recommended by the board of directors and is approved at a shareholders meeting by the same majority required for the initial election of an external director (as described above).

The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the Nasdaq Capital Market, may be extended indefinitely in increments of additional three-year terms, in each case provided that the audit committee and the board of directors of the company confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period(s) is beneficial to the company, and provided that the external director is reelected subject to the same shareholder vote requirements as if elected for the first time (as described above). Prior to the approval of the reelection of the external director at a general shareholders meeting, the company's shareholders must be informed of the term previously served by him or her and of the reasons why the board of directors and audit committee recommended the extension of his or her term.

External directors may be removed from office by a special general meeting of shareholders called by the board of directors, which approves such dismissal by the same shareholder vote percentage required for their election, after receiving the board of directors arguments for such removal, or by a court, in each case, only under limited circumstances, including ceasing to meet the statutory qualifications for appointment, or violating their duty of loyalty to the company. If an external directorship becomes vacant and there are fewer than two external directors on the board of directors at the time, then the board of directors is required under the Companies Law to call a shareholders meeting as soon as practicable to appoint a replacement external director.

Each committee of the board of directors that is authorized to exercise the powers of the board of directors must include at least one external director, except that the audit committee and the compensation committee must include all external directors then serving on the board of directors.

External directors may be compensated only in accordance with regulations adopted under the Companies Law.

Committees of the Board of Directors

Our board of directors has established four standing committees, the audit committee, the financial statement examination committee, the strategic committee, and the compensation committee.

Audit Committee

Our audit committee consists of Abraham Nahmias along with our two external directors, Ruhama Avraham and Jonathan Burgin. Mr. Burgin serves as Chairman of the 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. Under the Companies Law, the audit committee may not include the Chairman of the board of directors, a controlling shareholder of the company or a relative of a controlling shareholder, a director employed by or providing services on a regular basis to the company, to a controlling shareholder or to an entity controlled by a controlling shareholder or a director most of whose livelihood depends on a controlling shareholder.

In addition, under the Companies Law, the audit committee of a publicly traded company must consist of a majority of unaffiliated directors. In general, an "unaffiliated director" under the Companies Law is defined as either an external director or as a director who meets the following criteria:

- he or she meets the qualifications for being appointed as an external director, except for the requirement that the director be an Israeli resident (which does not apply to companies whose securities have been offered outside of Israel or are listed outside of Israel); and
- he or she has not served as a director of the company for a period exceeding nine consecutive years, provided that, for this purpose, a break of less than two years in service shall not be deemed to interrupt the continuation of the service.

The Companies Law further requires that generally, any person who does not qualify to be a member of the audit committee may not attend the audit committee's meetings and voting sessions, unless such person was invited by the chairperson of the committee for the purpose of presenting on a specific subject; provided, however, that an employee of the company who is not the controlling shareholder or a relative of a controlling shareholder may attend the discussions of the committee, provided that any resolutions approved at such meeting are voted on without his or her presence. A company's legal advisor and company secretary who are not the controlling shareholder or a relative of a controlling shareholder may attend the meeting and voting sessions, if required by the committee.

The quorum required for the convening of meetings of the audit committee and for adopting resolutions by the audit committee is a majority of the members of the audit committee, provided such majority is comprised of a majority of independent directors, at least one of which is an external director.

Under the Nasdaq Capital Market corporate governance rules, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise.

All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq Capital Market corporate governance rules. Our board of directors has determined that Jonathan Burgin and Abraham Nahmias are audit committee financial experts as defined by the SEC rules, have the requisite financial sophistication as required by the Nasdaq Capital Market corporate governance rules.

Each of the members of the audit committee is deemed “independent” as such term is defined in Rule 10A-3(b)(1) under the Exchange Act, according to which an audit committee member is barred from accepting any consulting, advisory or other compensatory fee from the company or any subsidiary thereof, other than in the member’s capacity as a member of the board of directors, and may not be an affiliated person of the company or any subsidiary of the company apart from his or her capacity as a member of the board of directors and any committee of the board of directors.

Our board of directors has adopted an audit committee charter which became effective upon the listing of our ADSs and warrants on the Nasdaq Capital Market that sets forth the responsibilities of the audit committee consistent with the rules of the SEC and the listing rules of the Nasdaq, as well as the requirements for such committee under the Companies Law, including the following:

- overseeing 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 the business management practices of our company, including in consultation with our internal auditor or the independent auditor, and making recommendations to the board of directors to improve such practices;
- determining the approval process for transactions that are ‘non-negligible’ (i.e., transactions with a controlling shareholder that are classified by the audit committee as non-negligible, even though they are not deemed extraordinary transactions), as well as determining which types of transactions would require the approval of the audit committee, optionally based on criteria which may be determined annually in advance by the audit committee;
- 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 Companies Law) (see “— Approval of Related Party Transactions under Israeli Law”);
- examining the working plan of the internal auditor, where the board of directors approves such working plan, before its submission to our board of directors and proposing amendments thereto;
- 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 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 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” below), unless at the time of the approval a majority of the committee’s members are present, which majority consists of unaffiliated directors including at least one external director.

Financial Statement Examination Committee

Under the Israeli Companies Law, the board of directors of a public company must appoint a financial statement examination committee, which consists of members with accounting and financial expertise or the ability to read and understand financial statements, unless the board of directors of such company opts for an exemption under relevant regulations promulgated under the Israeli Companies Law, as our board of directors has done. Accordingly, in July 2016, our board of directors adopted a resolution that our audit committee is assigned the responsibilities and duties of the financial statements examination committee. From time to time, as necessary and required to approve our financial statements, the audit committee holds separate meetings, prior to the scheduled meetings of the entire board of directors regarding financial statement approval. The function of a financial statements examination committee is to discuss and provide recommendations to its board of directors (including the report of any deficiency found) with respect to the following issues: (1) estimations and assessments made in connection with the preparation of financial statements; (2) internal controls related to the financial statements; (3) completeness and propriety of the disclosure in the financial statements; (4) the accounting policies adopted and the accounting treatments implemented in material matters of the company; (5) value evaluations, including the assumptions and assessments on which evaluations are based and the supporting data in the financial statements. Our independent auditors and our internal auditors are invited to attend all meetings of audit committee when it is acting in the role of the financial statements examination committee.

Strategic Committee

Our strategic committee consists of Dr. Michael Berelowitz, David Braun, Ruth Ben-Yakar, Nuriel Chirich Kasbian, Shai Yarkoni and Jonathan Burgin. Mr. Berelowitz serves as Chairman of the strategic committee

The strategic committee was established by our board of directors in May 2018 in order to determine our strategy for upcoming years. The strategic committee is not a mandatory committee according to the Israeli Companies Law and has an advisory role.

Compensation Committee and Compensation Policy

Our compensation committee consists of Abraham Nahmias along with our two external directors, Ruhama Avraham and Jonathan Burgin. Mr. Burgin serves as Chairman of the compensation committee.

The duties of the compensation committee include the recommendation to the company’s 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 for approval by the company’s shareholders, which approval requires a Special Approval for Compensation as described below under “— Approval of Related Party Transactions under Israeli Law—Fiduciary Duties of Directors and Executive Officers”.

Under the Companies Law, the board of directors of a public company must appoint a compensation committee and adopt a compensation policy. The compensation committee must be comprised of at least three directors, including all of the external directors, who must constitute a majority of the members of the compensation committee, and one of the external directors must serve as Chairman of the committee. However, subject to certain exceptions, Israeli companies whose securities are traded on stock exchanges such as the Nasdaq Capital Market, and who do not have a controlling shareholder, do not have to meet this majority requirement; provided, however, that the compensation committee meets other Companies Law composition requirements, as well as the requirements of the jurisdiction where the company’s securities are traded. Each compensation committee member that is not an external director must be a director whose compensation does not exceed an amount that may be paid to an external director. The compensation committee is subject to the same Companies Law restrictions as the audit committee as to who may not be a member of the committee.

The compensation policy must be based on certain considerations, must include certain provisions and must refer to certain matters as set forth in the Companies Law. The compensation policy must be approved by the company’s board of directors after considering the recommendations of the compensation committee. In addition, the compensation policy needs to be approved by the company’s shareholders by a simple majority, provided that (1) such majority includes a majority of the votes cast by the shareholders who are not controlling shareholders and who do not have a personal interest in the matter, present and voting (abstentions are disregarded) or (2) the votes cast by shareholders who are not controlling shareholders and who do not have a personal interest in the matter who were present and voted against the compensation policy, constitute two percent or less of the voting power of the company.

To the extent a compensation policy is not approved by shareholders at a duly convened shareholders meeting, the board of directors of a company may override the resolution of the shareholders following a re-discussion of the matter by the board of directors and the compensation committee and for specified reasons, and after determining that despite the rejection by the shareholders, the adoption of the compensation policy is for the benefit of the company.

A compensation policy that is for a period of more than three years must be approved in accordance with the above procedure every three years.

Notwithstanding the above, the amendment of existing terms of office and employment of office holders (other than directors or controlling shareholders and their relatives, who serve as office holders) requires the approval of only the compensation committee, if such committee determines that the amendment is not material in relation to its existing terms.

Pursuant to the Companies Law, following the recommendation of our compensation committee, our board of directors approved our compensation policy, and our shareholders, in turn, approved our amended and restated compensation policy at our annual general meeting of shareholders that was held in July 2018.

The 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 the nature of its operations. 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 ratio between the cost of the terms of employment of an office holder and the cost of the compensation of the other employees of the company, including those employed through manpower companies, in particular the ratio between such cost and the average and median compensation of the other employees of the company, as well as the impact such disparities may have on the work relationships in the company;
- the possibility of reducing variable compensation, if any, at the discretion of the board of directors; and the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, if any, 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 contribution 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:

- a 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) fulfilling the 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 compensation committee's responsibilities include:

- reviewing and recommending overall compensation policies with respect to our Chief Executive Officer and other executive officers;
- reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers including evaluating their performance in light of such goals and objectives;
- reviewing and approving the granting of options and other incentive awards; and
- reviewing, evaluating and making recommendations regarding the compensation and benefits for our non-employee directors.

Internal Auditor

Under the Companies Law, the board of directors of an Israeli public company must appoint an internal auditor in accordance with the recommendation of the audit committee. An internal auditor may not be:

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

The role of the internal auditor is 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. On May 31, 2016, we appointed Sapir Guy as our internal auditor. Sapir Guy is a certified internal auditor and a partner at Kesselman & Kesselman (PwC), a certified public accounting firm in Israel.

The Chairman of the board of directors will be the direct supervisor of the internal auditor, unless the board of directors shall determine otherwise, according to our articles of association and the Companies Law. The internal auditor is required to submit his or her findings to the audit committee, unless specified otherwise by the board of directors.

Each director, except external directors, will hold office until the annual general meeting of our shareholders for the year in which his or her term expires, unless he or she is removed by a simple majority vote of our shareholders at a general meeting of our shareholders or upon the occurrence of certain events, in accordance with the Companies Law and our amended and restated articles of association.

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 "Directors and Senior Management" above 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 any such action.

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 board of directors any personal interest that he or she may be aware of and all related material information or documents concerning any existing or proposed transaction with 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. A personal interest includes an interest of any person in an act or transaction of a company, including a 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, obligated 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 a 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. Our articles of association do not provide otherwise. 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 the 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 the approval of a majority vote of the shares present and voting at a shareholders meeting, 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 (excluding abstaining shareholders); 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. We refer to this as the Special Approval for Compensation. 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 Approval for Compensation.

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. Generally, 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. In the event a majority of the members of the board of directors have a personal interest in the approval of a transaction, then the approval thereof shall also require the approval of the shareholders.

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

Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. In the context of a transaction involving a shareholder of the company, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 50% of the voting rights in the company. For this purpose, the holdings of all shareholders who have a personal interest in the same transaction will be aggregated. The approval of the audit committee or the compensation committee, as the case may be, the board of directors and the shareholders of the company, 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 (collectively referred to as a Transaction with a Controlling Shareholder). In addition, such shareholder approval requires one of the following, which we refer to as a Special Majority:

- at least a majority of the shares held by all shareholders who do not have a personal interest in the transaction and who are present and voting at the meeting approving the transaction, excluding abstentions; or
- the shares voted against the transaction by shareholders who have no personal interest in the transaction and who are present and voting at the meeting do not exceed 2% of the voting rights in the company.

To the extent that any such Transaction with a Controlling Shareholder is for a period extending beyond three years, approval 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, a relative of a controlling shareholder, or a director 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 and subject Company's Compensation Policy.

Shareholder Duties

Pursuant to the Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at a general meeting and at shareholder class meetings with respect to the following matters:

- an amendment to the company's articles of association;
- an increase of the company's authorized share capital;
- a merger; or
- the approval of related party transactions and acts of office holders that require shareholder approval.

In addition, a shareholder also has a general duty to refrain from discriminating against other shareholders.

Certain shareholders also have a duty of fairness toward the company. These shareholders include any controlling shareholder, any shareholder who knows that he or she has the power to determine the outcome of a shareholder vote at a general meeting or a shareholder class meeting and any shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or other power towards the company. The Companies Law does not define the substance of the duty of fairness, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

Exculpation, Insurance and Indemnification of Directors and Officers

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our articles of association include such a provision. The company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Companies Law, a company may indemnify an office holder in respect of the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification, which ours do:

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be reasonably foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (a) no indictment was filed against such office holder as a result of such investigation or proceeding; and (b) no financial liability, such as a criminal penalty, was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a monetary sanction; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Companies Law and the Israeli Securities Law 5728-1968, or the Israeli Securities Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and
- a financial liability imposed on the office holder in favor of a third party.

Under our articles of association, we may insure an office holder against the aforementioned liabilities as well as the following liabilities:

- a breach of duty of care to the company or to a third party;
- any other action against which we are permitted by law to insure an office holder;

- expenses incurred and/or paid by the office holder in connection with an administrative enforcement procedure under any applicable law including the Efficiency of Enforcement Procedures in the Securities Authority Law (legislation amendments), 5771-2011, or the Efficiency of Enforcement Procedures, and the Israeli Securities Law, which we refer to as an Administrative Enforcement Procedure, and including reasonable litigation expenses and attorney fees; and
- a financial liability in favor or a victim of a felony pursuant to Section 52ND of the Israeli Securities Law.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach arising solely out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, civil fine, administrative fine or ransom or levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders. See “—Approval of Related Party Transactions under Israeli Law.”

Our articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Companies Law and the Israeli Securities Law, including expenses incurred and/or paid by the office holder in connection with an Administrative Enforcement Procedure.

We have entered into agreements with each of our directors and executive officers exculpating them, to the fullest extent permitted by law and our articles of association, and undertaking to indemnify them to the fullest extent permitted by law and our articles of association. This indemnification will be limited to events determined as foreseeable by the board of directors based on our activities, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances.

The maximum indemnification amount will be limited to an amount which shall not exceed 25% of our net assets based on our most recently audited or reviewed financial statements prior to actual payment of the indemnification amount. Such maximum amount is in addition to any amount paid (if paid) under insurance and/or by a third-party pursuant to an indemnification arrangement.

In the opinion of the SEC, indemnification of directors and office holders for liabilities arising under the Securities Act, however, is against public policy and therefore unenforceable.

We have obtained directors’ and officers’ liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Companies Law.

D. Employees.

As of December 31, 2018, we had twenty-eight full-time employees. These employees are comprised of nineteen in research and development and nine employees in management, finance, business development and administration. From time to time, we also employ independent contractors to support our operations. Our employees are not represented by any collective bargaining agreements and we have never experienced an organized work stoppage. All of our employees are located in Israel other than one employee who is located in the United States.

E. Share Ownership.

Stock Option Plans

Equity Compensation Plan

We maintain our 2014 Collect Option Plan, which was originally adopted by our board of directors in February 2014 and is scheduled to expire in February 2024. The 2014 Collect Option Plan provides for the grant of options to our directors, officers, employees, consultants, advisers and service providers. As of December 31, 2018, options to purchase 13,014,147 ordinary shares were outstanding and up to 1,548,784 ordinary shares are available for issuance. Of such outstanding options, options to purchase 5,536,637 ordinary shares are exercisable as of December 31, 2018, with a weighted average exercise price of NIS 1.18 per share, and will expire ten years from the date of grant, during the years 2024 – 2028.

The 2014 Collect Option Plan provides for options to be granted at the determination of our board of directors (which is entitled to delegate its powers under the 2014 Collect Option Plan to our compensation committee) in accordance with applicable laws. Upon termination of employment for any reason, other than in the event of death or disability or for cause, all unvested options will expire and all vested options at time of termination will generally be exercisable for 90 days following termination, subject to the terms of the 2014 Collect Option Plan and the governing option agreement. If we terminate a grantee for cause (as defined in the 2014 Collect Option Plan) the grantee's right to exercise all vested and unvested the options granted to him or her will expire immediately. Upon termination of employment due to death or disability, all the vested options at the time of termination will be exercisable for 12 months after date of termination, subject to the terms of the 2014 Collect Option Plan and the governing option agreement.

Pursuant to the 2014 Collect Option Plan, we may award options pursuant to Section 102 of the Israeli Income Tax Ordinance, or the Ordinance, and section 3(I) of the Ordinance, based on entitlement and compliance with the terms for receiving options under these sections of the Ordinance. Section 102 of the Ordinance provides to employees, directors and officers who are not controlling shareholders (i.e., such persons are not deemed to hold 10% of our share capital, or to be entitled to 10% of our profits or to appoint a director to our board of directors) and are Israeli residents, favorable tax treatment for compensation in the form of shares or options issued or granted, as applicable, to a trustee under the "capital gains track" for the benefit of the applicable employee, director or officer and are (or were) to be held by the trustee for at least two years after the date of grant or issuance. Options granted under Section 102 of the Ordinance will be deposited with a trustee appointed by us in accordance with Section 102 of the Ordinance and the relevant income tax regulations and guidelines, and will be granted in the employee income track or the capital gains track.

Options granted under the 2014 Collect Option Plan are subject to applicable vesting schedules and generally expire ten years from the grant date.

In the event that options allocated under the 2014 Collect Option Plan expire or otherwise terminate in accordance with the provisions of the 2014 Collect Option Plan, such expired or terminated options will become available for future grant awards and allocations under the 2014 Collect Option Plan. We have registered the ordinary shares available for issuance under the 2014 Collect Option Plan pursuant to a Registration Statement on Form S-8.

See also "Item 7. Major Shareholders and Related Party Transactions—A. Major Shareholders" below.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of our ordinary shares as of March 12, 2019 by:

- each of our directors and senior management;
- all of our directors and senior management as a group; and
- each person (or group of affiliated persons) known by us to be the beneficial owner of more than 5% of the outstanding ordinary shares.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to ordinary shares. Ordinary shares issuable under share options, warrants or other conversion rights currently exercisable or that are exercisable within 60 days after March 12, 2019 are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options, warrants or other conversion rights, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. Percentage of shares beneficially owned before this offering is based on 224,087,799 ordinary shares outstanding (which excludes 2,641,693 shares held in treasury) on March 12, 2019.

Except where otherwise indicated, and except pursuant to community property laws, we believe, based on information furnished by such owners, that the beneficial owners of the shares listed below have sole investment and voting power with respect to, and the sole right to receive the economic benefit of ownership of, such shares. The shareholders listed below do not have any different voting rights from any of our other shareholders. We know of no arrangements that would, at a subsequent date, result in a change of control of our Company.

	Number of Shares Beneficially	Percentage Ownership
Directors and Senior Management		
Kasbian Nuriel Chirich (1)	36,400,842	16.1%
Dr. Shai Yarkoni (2)	36,400,842	16.0%
Eyal Leibovitz (3)	1,656,783	*
Dr. Ronit Bakimer-Kleiner (4)	23,125	*
Andrew Sabatier (5)	120,000	*
Dr. Yael Kenan (6)	23,125	*
Dr. Amos Ofer (7)	-	-
Smadar Har Tuv (8)	100,000	*
Abraham Nahmias (9)	377,667	*
Ruth Ben Yakar (10)	211,000	*
Michael Berelowitz (11)	75,000	*
Ruhama Avraham (12)	46,875	*
David Braun (13)	46,875	*
Jonathan Burgin (14)	-	-
Directors and Senior Management as a group (14 persons)	39,081,292	17.2%
More than 5% Shareholders		
Ilan Holdings (M&I) Ltd. (15)	14,962,470	6.7%
Anson Funds Management L.P. (16)	16,600,016	7.6%
Sabby Volatility Warrant Master Fund, Ltd (17)	16,802,660	7.7%

* Less than 1%

- (1) Represents (i) 854,613 ADSs representing 17,092,267 ordinary shares owned by Mr. Chirich, (ii) 12,420 ADS representing 248,400 ordinary shares issuable upon exercise of warrants at an exercise price of \$7.50 per ADS and expiring on July 29, 2021, (iii) options to purchase 72,000 ordinary shares at an exercise price of NIS 1.90 per share and expiring on August 25, 2025, (iv) options to purchase 721,365 ordinary shares at an exercise price of NIS 1.20 per share and expiring on February 27, 2027, (v) options to purchase 158,178 ordinary shares at an exercise price of NIS 1.515 per share and expiring on March 12, 2028, and (vi) 33,333 ADS representing 666,667 ordinary shares issuable upon exercise of warrants at an exercise price of \$1.50 per ADS and expiring on February 12, 2024 and (v) 17,441,967 ordinary shares beneficially owned by Dr. Yarkoni over which Mr. Chirich has shared voting power pursuant to a voting agreement. Excludes options to purchase 1,195,897 ordinary shares that vest in more than 60 days from March 12, 2019.
- (2) Represents (i) 711,454 ADSs representing 14,229,073 ordinary shares owned by Dr. Yarkoni, (ii) 14,777 ADS representing 295,540 ordinary shares issuable upon exercise of warrants at an exercise price of \$7.50 per ADS and expiring on July 29, 2021, (iii) options to purchase 1,200,000 ordinary shares, at an exercise price of NIS 1.40 per share and expiring on September 8, 2024, (iv) options to purchase 72,000 ordinary shares at an exercise price of NIS 1.90 per share and expiring on August 26, 2025, (v) options to purchase 1,512,020 ordinary shares at an exercise price of NIS 1.20 per share and expiring on February 27, 2027, and (vi) 6,667 ADS representing 133,333 ordinary shares issuable upon exercise of warrants at an exercise price of \$1.50 per ADS and expiring on February 12, 2024 and (v) 18,958,875 ordinary shares beneficially owned by Mr. Chirich over which Dr. Yarkoni has shared voting power pursuant to a voting agreement. Excludes options to purchase 1,512,020 ordinary shares that vest in more than 60 days from March 12, 2019.
- (3) Represents (i) 3,708 ADSs representing 74,167 ordinary shares owned by Mr. Leibovitz, (ii) options to purchase 1,515,950 ordinary shares at an exercise price of NIS 0.819 per share and expiring on October 26, 2026, (iii) options to purchase 1,515,950 ordinary shares at an exercise price of NIS 0.819 per share and expiring on and November 20, 2027, and (iv) 3,333 ADS representing 66,667 ordinary shares issuable upon exercise of warrants at an exercise price of \$1.50 per ADS and expiring on February 12, 2024. Excludes options to purchase 528,137 ordinary shares that vest in more than 60 days from March 12, 2019.
- (4) Represents options to purchase 23,125 ordinary shares at an exercise price of NIS 1.444 per share and expiring on November 20, 2027. Excludes options to purchase 50,875 ordinary shares that vest in more than 60 days from March 12, 2019.
- (5) Represents (i) 3,000 ADSs representing 60,000 ordinary shares owned by Mr. Sabatier, and (ii) 3,000 ADS representing 60,000 ordinary shares issuable upon exercise of warrants at an exercise price of \$1.50 per ADS and expiring on February 12, 2024. Excludes options to purchase 2,044,080 ordinary shares that vest in more than 60 days from March 12, 2019.

- (6) Represents options to purchase 23,125 ordinary shares at an exercise price of NIS 1.361 per share and expiring on January 22, 2028. Excludes options to purchase 50,875 ordinary shares that vest in more than 60 days from March 12, 2019.
- (7) Excludes options to purchase 400,000 ordinary shares that vest in more than 60 days from March 12, 2019.
- (8) Represents options to purchase 100,000 ordinary shares at an exercise price of NIS 0.631 per share and expiring on January 26, 2027.
- (9) Represents (i) 133,333 ordinary shares owned by Mr. Abraham Nahmias, (ii) options to purchase 72,000 ordinary shares at an exercise price of NIS 1.90 per share and expiring on August 26, 2025, (iii) options to purchase 39,000 ordinary shares at an exercise price of NIS 1.20 per share and expiring on February 27, 2027, and (iv) 6,667 ADS representing 133,333 ordinary shares issuable upon exercise of warrants at an exercise price of \$1.50 per ADS and expiring on February 12, 2024. Excludes options to purchase 39,000 ordinary shares that vest in more than 60 days from March 12, 2019.
- (10) Represents (i) options to purchase 100,000 ordinary shares at an exercise price of NIS 1.40 per share and expiring on September 28, 2024, (ii) options to purchase 72,000 ordinary shares at an exercise price of NIS 1.90 per share and expiring on August 26, 2025, and (iii) options to purchase 39,000 ordinary shares at an exercise price of NIS 1.20 per share and expiring on February 27, 2027. Excludes options to purchase 39,000 ordinary shares that vest in more than 60 days from March 12, 2019.
- (11) Represents options to purchase 75,000 ordinary shares at an exercise price of NIS 1.20 per share and expiring on February 27, 2027. Excludes options to purchase 75,000 ordinary shares that vest in more than 60 days from March 12, 2019.
- (12) Represents options to purchase 46,875 ordinary shares at an exercise price of NIS 1.437 per share and expiring on February 12, 2027. Excludes options to purchase 103,125 ordinary shares that vest in more than 60 days from March 12, 2019.
- Represents options to purchase 46,875 ordinary shares at an exercise price of NIS 1.437 per share and expiring on February 12, 2027. Excludes options to purchase 103,125 ordinary shares that vest in more than 60 days from March 12, 2019.
- (13)
- (14) Excludes options to purchase 150,000 ordinary shares that vest in more than 60 days from March 12, 2019
- (15) Based on information contained in a Schedule 13G/A filed with the SEC on February 14, 2019 jointly by Ilan Holdings (M&I) Ltd. and Arrow Pride (Eran Ilan) (together, the "Reporting Persons"), the Reporting Persons have the sole power to vote and dispose of 14,489,100 ordinary shares.
- (16) Based on information contained in a Schedule 13G filed with the SEC on February 19, 2019 jointly by Anson Funds Management LP (d/b/a Anson Group), or AFM, Anson Management GP LLC or AM, Bruce R. Winson, the principal of AFM and AM, Anson Advisors Inc. (d/b/a Anson Funds), or AA, Amin Nathoo, a director of AA, and Moez Kassam, a director of AA. AMF and AA serve as co-investment advisors to a private fund, or the Fund and may direct the vote and disposition of the 16,600,016 ordinary shares represented by ADSs held by the Fund. As the general partner of AFM, AM may direct the vote and disposition of the 16,600,016 ordinary shares represented by ADSs held by the Fund. As the principal of AFM and AM, Mr. Winson may direct the vote and disposition of the 16,600,016 ordinary shares represented by ADSs held by the Fund. As directors of AA, Mr. Nathoo and Mr. Kassam may each direct the vote and disposition of the 16,600,016 ordinary shares represented by ADSs held by the Fund.
- (17) Based partially on information contained in a Schedule 13G filed with the SEC on February 12, 2019 jointly by Sabby Healthcare Master Fund, Ltd., or Sabby HMF, Sabby Volatility Warrant Master Fund, Ltd., or Sabby VWMF, Sabby Management, LLC, or Sabby Management, and Hal Mintz. Sabby HMF and Sabby VWMF beneficially own 0 and 16,802,660 Ordinary shares, respectively, and Sabby Management and Mr. Mintz each beneficially own 16,802,660 ordinary shares. Sabby Management and Mr. Mintz do not directly own any ordinary shares, but each indirectly owns 16,802,660 ordinary shares. Sabby Management indirectly owns 16,802,660 ordinary shares because it serves as the investment manager of Sabby HMF and Sabby VWMF. Mr. Mintz indirectly owns 16,802,660 ordinary shares in his capacity as manager of Sabby Management.

To our knowledge, from the date immediately prior to our U.S. initial public offering on August 3, 2016 to March 12, 2019, the ownership percentage of Kasbian Nuriel Chirich decreased by 12.5% from 20.3% to 7.8%, the ownership percentage of Shai Yarkoni decreased by 11.6% from 18.1% to 6.5% during such period (in each case of Mr. Chirich and Dr. Yarkoni without giving effect to the voting agreement they are party to), the ownership percentage of Michael Ilan Management and Investments Ltd. (assuming such entity is affiliated with Ilan Holdings (M&I) Ltd.) decreased by 14.3% from 20.9% to 6.7%, the ownership percentage of Nadir Askenasy decreased from 16.9% to under 5%. Anson Funds Management L.P. and Sabby Volatility Warrant Master Fund, Ltd became more than 5% shareholders as a result of their participation in our follow-on underwritten public offering in February 2019. Sabby has held more than 5% of our outstanding shares in the past.

Bank of New York Mellon, or BNY, is the holder of record for our ADR program, pursuant to which each ADS represents 20 ordinary shares. As of March 12, 2019, BNY held 217,664,440 ordinary shares representing 97% of the outstanding share capital held at that date. Certain of these ordinary shares were held by brokers or other nominees. As a result, the number of holders of record or registered holders in the United States is not representative of the number of beneficial holders or of the residence of beneficial holders.

None of our shareholders has different voting rights from other shareholders. To our knowledge, we are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of us.

B. Related Party Transactions

The following is a description of the transactions with related parties to which we are party and which were in effect within the past three fiscal years. The descriptions provided below are summaries of the terms of such agreements and do not purport to be complete and are qualified in their entirety by the complete agreements.

We believe that we have executed all of our transactions with related parties on terms no less favorable to us than those we could have obtained from unaffiliated third parties. See “Board Practices — Approval of Related Party Transactions under Israeli Law.”

Founders Agreement and Voting Agreement

On June 1, 2011, Kasbian Nuriel Chirich, our Chairman, Dr. Shai Yarkoni, our Chief Executive Officer and director, and Dr. Nadir Askenasy, our former Chief Technology Officer entered into a founders agreement with respect to Collect Biotherapeutics, our subsidiary. Subsequently, on May 16, 2013, the parties to the founders agreement entered into an agreement pursuant to which it was agreed that the founders agreement will apply to the parties with respect to us following the merger which closed on July 1, 2013.

Under the founders agreement, each founder holding at least 30% of our share capital shall be entitled to recommend the appointment of one director (and remove any director so appointed). The founders agreement also provides pre-emptive rights, rights of first refusal, co-sale rights and bring along rights among the founders subject to certain permitted transfers.

Under a voting agreement dated August 14, 2017, among Dr. Shai Yarkoni and Kasbian Nuriel, the parties agreed to coordinate their votes with respect to any vote taken of our shareholders.

Indemnification Agreements

Our articles of association permit us to exculpate, indemnify and insure our directors and officeholders to the fullest extent permitted by the Companies Law. We have obtained directors’ and officers’ insurance for each of our officers and directors. We have entered into indemnification and exculpation agreements with each of our current office holders and directors, exculpating them to the fullest extent permitted by the law and our articles of association and undertaking to indemnify them to the fullest extent permitted by the law and our articles of association, including with respect to liabilities resulting from this offering, to the extent such liabilities are not covered by insurance. See “Management Exculpation, Insurance and Indemnification of Directors and Officers.”

Employment and Service Agreements

We have employment, service or related agreements with certain members of senior management and directors. See “Item 6. Directors, Senior Management and Employees—B. Compensation”.

2019 Underwritten Public Offering

Certain of our officers and directors participated in our follow on underwritten offering in February 2019. See “Item 10. Additional Information—Material Contracts—2019 Underwritten Public Offering”.

Options

We have granted options to purchase our ordinary shares to certain of our officers and directors. See “Item 6. Directors, Senior Management and Employees—B. Compensation” and “Item 7. Major Shareholders and Related Party Transactions—A. Major Shareholders”. We describe our option plans under “Item 6. Directors, Senior Management and Employees—E. Share Ownership” and “Item 7. Major Shareholders and Related Party Transactions—A. Major Shareholders”.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION.

A. Consolidated Statements and Other Financial Information.

See “Item 18. Financial Statements.”

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are currently not a party to any material legal or administrative proceedings and except as set forth below, are not aware of any pending or threatened material legal or administrative proceedings against us.

Dividends

We have never declared or paid cash dividends to our shareholders. Currently, we do not intend to pay cash dividends. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, applicable Israeli law and other factors our board of directors may deem relevant. In addition, the distribution of dividends is limited by Israeli law, which permits the distribution of dividends only out of distributable profits. See “Item 10. Additional Information—B. Articles of Association—Dividends.” See “Item 10. Additional Information—E. Taxation—Israeli Tax Considerations and Government Programs.”

If we pay any dividends, we will also pay such dividends to the ADS holders to the same extent as holders of our ordinary shares, subject to the terms of the deposit agreement, including the fees and expenses payable thereunder. No dividends will accrue for any unexercised warrants. Cash dividends on our ordinary shares, if any, will be paid to ADS holders in U.S. dollars.

B. Significant Changes

No significant change, other than as otherwise described in this annual report on Form 20-F, has occurred in our operations since the date of our consolidated financial statements included in this annual report on Form 20-F.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

On July 29, 2016, our ADSs and warrants, commenced trading on the Nasdaq Capital Market under the symbols “APOP” and “APOPW”, respectively. From 1990 to September 3, 2017, our shares were traded on the TASE.

B. Plan of Distribution

Not applicable.

C. Markets

Our ADSs and warrants are listed on the Nasdaq Capital Market.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Articles of Association

Our registration number with the Israeli Registrar of Companies is 520036484.

Articles of Association

The following are summaries of material provisions of our articles of association, as amended from time to time, and the Companies Law insofar as they relate to the material terms of our ordinary shares.

Purposes and Objects of the Company

Our purpose is set forth in Section 2 of our articles of association and includes every lawful purpose.

Registration Number

Our number with the Israeli Registrar of Companies is 520036484.

Voting Rights

Holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders at a shareholders meeting. Shareholders may vote at shareholders meetings either in person, by proxy or by written ballot. Israeli law does not allow public companies to adopt shareholder resolutions by means of written consent in lieu of a shareholders meeting. The board of directors shall determine and provide a record date for each shareholders meeting and all shareholders at such record date may vote. Unless stipulated differently in the Companies Law or in the articles of association, all shareholders' resolutions shall be approved by a simple majority vote. Except as otherwise disclosed herein, an amendment to our articles of association requires the prior approval of a simple majority of our shares represented and voting at a general meeting.

Transfer of Shares

Our ordinary shares that are fully paid for are issued in registered form and may be freely transferred under our articles of association, unless the transfer is restricted or prohibited by applicable law or the rules of a stock exchange on which the shares are traded. See "Shares Eligible for Future Sale" with respect to the applicable U.S. law. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our articles of association or Israeli law, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

The Powers of the Directors

Our board of directors directs our policy and supervises the performance of our Chief Executive Officer. Pursuant to the Companies Law and our articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our articles of association to be exercised or taken by our shareholders.

Amendment of Share Capital

Our 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 or special meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings and profits, require a resolution of our board of directors and court approval.

Dividends

Under Israeli law, we may declare and pay dividends only if, upon the determination of our board of directors, there is no reasonable concern that the distribution will prevent us from being able to meet the terms of our existing and foreseeable obligations as they become due. Under the Companies Law, the distribution amount is further limited to the greater of retained earnings or earnings generated over the two most recent years legally available for distribution 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 distribution. In the event that we do not have retained earnings or earnings generated over the two most recent years legally available for distribution, we may seek the approval of the court in order to distribute a dividend. The court may approve our request if it determines that there is no reasonable concern that the payment of a dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

Shareholders Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year and in any event 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 as special meetings. Our board of directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Companies Law and our articles of association provide that our board of directors is required to convene a special meeting upon the written request of (1) any two of our directors or one quarter of the directors then in office; or (2) one or more shareholders holding, in the aggregate either (a) 5% of our issued share capital and 1% of our outstanding voting power, or (b) 5% of our outstanding voting power.

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 and in accordance with the Companies Law and its Regulations. Furthermore, the Companies Law and our articles of association require 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 and dismissal of directors and external directors;
- approval of acts and transactions requiring general meeting approval pursuant to the Companies Law;
- director compensation, indemnification and change of the principal executive officer;
- increases or reductions of our authorized share capital;
- 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; and
- authorization of the Chairman of the board of directors or his relative to act as the company's Chief Executive Officer or act with such authority; or authorization of the company's Chief Executive Officer or his relative to act as the Chairman of the board of directors or act with such authority.

The Companies Law requires that a notice of any annual or special shareholders meeting be provided at least 21 days prior to the meeting. In the event the agenda of the meeting includes the matters specified under bullets 3, 4, 5, 7 and 9 above, or the approval of transactions with office holders or interested or related parties, a notice must be provided at least 35 days prior to the meeting.

The Companies Law does not allow shareholders of publicly traded companies to approve corporate matters by written consent. Consequently, our articles of association do not allow shareholders to approve corporate matters by written consent.

Pursuant to our 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.

Quorum

The quorum required for our general meetings of shareholders consists of two or more shareholders present in person, by proxy or by other voting instrument in accordance with the Companies Law and our articles of association who hold or represent, in the aggregate, at least 33 1/3% of the total outstanding voting rights, within half an hour from the appointed time.

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

Resolutions

Our articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by applicable law.

Israeli law provides that a shareholder of a public company may vote in a meeting and in a class meeting by means of a written ballot in which the shareholder indicates how he or she votes on resolutions relating to the following matters:

- an appointment or removal of directors;
- an approval of transactions with office holders or interested or related parties, that require shareholder approval;
- an approval of a merger;
- the authorization of the Chairman of the board of directors or his relative to act as the company's Chief Executive Officer or act with such authority; or the authorization of the company's Chief Executive Officer or his relative to act as the Chairman of the board of directors or act with such authority;
- any other matter that is determined in the articles of association to be voted on by way of a written ballot. Our articles of association do not stipulate any additional matters; and
- other matters which may be prescribed by Israel's Minister of Justice.

The provision allowing the vote by written ballot does not apply where the voting power of the controlling shareholder is sufficient to determine the vote.

The Companies Law provides that a shareholder, in exercising his or her rights and performing his or her obligations toward the company and its other shareholders, must act in good faith and in a customary manner, and avoid abusing his or her power. This is required when voting at general meetings on matters such as changes to the articles of association, increasing the company's registered capital, mergers and approval of certain interested or related party transactions. A shareholder also has a general duty to refrain from depriving any other shareholder of its rights as a shareholder. In addition, any controlling shareholder, any shareholder who knows that its vote can determine the outcome of a shareholder vote and any shareholder who, under such company's articles of association, can appoint or prevent the appointment of an office holder or other power towards the company, is required to act with fairness towards the company. The Companies Law does not describe the substance of this duty except that the remedies generally available upon a breach of contract will also apply to a breach of the duty to act with fairness, and, to the best of our knowledge, there is no binding case law that addresses this subject directly.

Under the Companies Law, unless provided otherwise in a company's articles of association, a resolution at a shareholders meeting requires approval by a simple majority of the voting rights represented at the meeting, in person, by proxy or written ballot, and voting on the resolution. Generally, a resolution for the voluntary winding up of the company requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by written ballot and voting on the resolution.

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.

Access to Corporate Records

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

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the target company's 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 same class for the purchase of all of the issued and outstanding shares of the same 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, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer). However, a shareholder that had its shares so transferred may petition the court within six months from the date of acceptance of the full tender offer, whether or not such shareholder agreed to the tender or not, to determine whether the tender offer was for less than fair value and whether the fair value should be paid as determined by the court unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights, so long as prior to the acceptance of the full tender offer, the acquirer and the company disclosed the information required by law in connection with the full tender offer. If the shareholders who did not accept the tender offer hold 5% 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 a public Israeli company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company, unless one of the exemptions in the Companies Law is met. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser would become a holder of 45% or more of the voting rights in the company, if there is no other shareholder of the company who holds 45% or more of the voting rights in the company, unless one of the exemptions in the Companies Law is met.

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) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer.

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.

Under regulations enacted pursuant to the Companies Law, the above special tender offer requirements may not apply to companies whose shares are listed for trading on a foreign stock exchange if, among other things, the relevant foreign laws or the rules of the stock exchange, include provisions limiting the percentage of control which may be acquired or that the purchaser is required to make a tender offer to the public. However, the ISA's opinion is that such leniency does not apply with respect to companies whose shares are listed for trading on stock exchanges in the United States, including the Nasdaq Capital Market, which do not provide for sufficient legal restrictions on obtaining control or an obligation to make a tender offer to the public, therefore the special tender offer requirements shall apply to such companies.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, a majority of each party's shares voted on the proposed merger at a shareholders meeting called with at least 35 days' prior notice.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person who holds 25% or more of the outstanding shares or the right to appoint 25% or more of the directors of the other party, vote against the merger. If the transaction would have been approved 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.

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

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

Antitakeover Measures

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights, distributions or other matters and shares having preemptive rights. As of the date of this annual report on Form 20-F, we do not have any authorized or issued shares other than our ordinary shares. In the future, if we do create and issue a class of shares other than ordinary shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of the holders of a majority of our shares at a general meeting. Shareholders voting in such meeting will be subject to the restrictions provided in the Companies Law as described above.

C. Material Contracts

Except as set forth below, we have not entered into any material contract within the two years prior to the date of this annual report on Form 20-F, other than contracts entered into in the ordinary course of business, or as otherwise described herein in “Item 4. Information on the Company—A. History and Development of the Company” above, “Item 4. Information on the Company—B. Business Overview” above, and “Item 7. Major Shareholders and Related Party Transactions—A. Major Shareholders” or “Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions” above.

September 2017 Financing

On September 7, 2017, we entered into Securities Purchase Agreements, or the 2017 Purchase Agreements, with certain accredited investors providing for the issuance of an aggregate of 531,136 ADSs in a registered direct offering at a purchase price of \$8.10 per ADS for aggregate gross proceeds of approximately \$4.3 million. The offering closed on September 11, 2017.

In addition, under the 2017 Purchase Agreements, the investors received unregistered warrants to purchase an aggregate of 265,568 ADSs. The warrants were exercisable immediately for a period of twelve months from the date of issuance at an exercise price of \$12.07 per ADS, subject to adjustment as set forth therein. The warrants could exercised on a cashless basis if there is no effective registration statement registering the ADSs underlying the warrants. The warrants have since expired.

The 2017 Purchase Agreements also contained representations, warranties, indemnification and other provisions customary for transactions of this nature.

We also entered into a letter agreement with Wainwright dated September 6, 2017, pursuant to which Wainwright agreed to serve as the placement agent for the Company in connection with the offering. We paid Wainwright a cash placement fee equal to 7% of the aggregate purchase price for the ADSs placed by the placement agent, plus a non-accountable expense allowance of \$15,000 and up to \$30,000 for certain expenses. Wainwright also received compensation warrants on substantially the same terms as the investors in the offering, except the exercise price shall be \$10.125 per ADS, in an amount equal to 5% of the aggregate number of ADSs sold in the offering that were placed by the placement agent. Those warrants have since expired.

January 2018 Financing

On January 29, 2018, we entered into Securities Purchase Agreements, or the 2018 Purchase Agreements, with certain institutional investors providing for the issuance of an aggregate of 484,848 ADSs in a registered direct offering at a purchase price of \$8.25 per ADS for aggregate gross proceeds of approximately \$4.0 million. The offering closed on January 31, 2018.

In addition, under the 2018 Purchase Agreements, the investors received unregistered warrants to purchase an aggregate of 266,667 ADSs. The warrants may be exercised immediately for a period of twelve months from the earlier of (i) the effectiveness date of a registration statement registering the shares underlying the warrants, and (ii) 6 months from the issuance date of the warrants, subject to adjustment as set forth therein. The warrants may be exercised on a cashless basis if there is no effective registration statement registering the ADSs underlying the warrants.

Under the 2018 Purchase Agreements, we agreed to use best efforts to file, as soon as practicable (and in any case by February 28, 2018), a registration statement with the SEC registering the resale of the ordinary shares underlying the ADSs issuable upon exercise of the warrants and to use best efforts to cause such registration statement to be declared effective within 60 days following the closing date and to keep such registration statement effective at all times until no purchaser owns any underlying ordinary shares issuable upon exercise of the warrants. If such registration statement is not declared effective within 60 days of the closing date, we agreed to pay monthly registration delay payments of 1.5% of the purchase price paid by the investors up to an aggregate of 8% until such time that the registration statement is declared effective by the SEC.

Further, under the 2018 Purchase Agreements, we agreed not to enter into any agreement to issue or announce the issuance or proposed issuance of any ADSs, ordinary shares or ordinary share equivalents for a period of 45 days following the closing of the offering, subject to certain customary exceptions. In addition, the 2018 Purchase Agreements provide that for a period of one year following the closing of the offering, we will not effect or enter into an agreement to effect a “variable rate transaction” as defined in the 2018 Purchase Agreements.

The 2018 Purchase Agreements also contains representations, warranties, indemnification and other provisions customary for transactions of this nature.

We also entered into a letter agreement, or the 2018 Placement Agent Agreement, with Wainwright dated January 15, 2018, pursuant to which Wainwright agreed to serve as the placement agent for us in connection with the offering. Under the letter agreement, we paid the Placement Agent a cash placement fee equal to 7% of the aggregate purchase price for the ADSs placed by the placement agent, plus a non-accountable expense allowance of \$25,000. Wainwright also received compensation warrants on substantially the same terms as the investors in the offering, except the exercise price shall be \$10.31 per ADS, in an amount equal to 5% of the aggregate number of ADSs sold in the offering that were placed by the placement agent.

2019 Underwritten Public Offering

On February 7, 2019, we entered into an Underwriting Agreement, or the Underwriting Agreement, with A.G.P./Alliance Global Partners as representative of the underwriters, relating to an underwritten public offering of (a) 1,889,000 units, consisting of (i) one ADS, and (ii) one warrant to purchase one ADS, at a public offering price of \$1.50 per unit, and (b) 2,444,800 pre-funded units, each consisting of (i) one pre-funded warrant to purchase one ADS, and (ii) one Warrant, at a public offering price of \$1.49 per pre-funded unit. The offering of the units and the pre-funded units closed on February 12, 2019.

The pre-funded units were issued and sold to purchasers whose purchase of units in the offering would otherwise result in the purchaser, together with their affiliates and certain related parties, beneficially owning more than 4.99% (or at the election of the purchaser, 9.99%) of our outstanding ordinary shares immediately following the consummation of the offering, if they so choose. Each pre-funded warrant contained in a pre-funded unit is immediately exercisable for one ADS at an exercise price of \$0.01 per share and will remain exercisable until exercised in full. The warrant included in the units and the pre-funded units is immediately exercisable at a price of \$1.50 per ADS, subject to adjustment in certain circumstances, and will expire five years from the date of issuance. The ADSs included in the units or pre-funded warrants included in the pre-funded units, as the case may be, and the warrants were offered together, but the securities contained in the units or pre-funded units were issued separately.

We also granted the underwriters a 45-day option to purchase up to an additional 650,070 ADSs and/or 650,070 warrants to purchase up to an additional 650,070 ADSs. The underwriters partially exercised their over-allotment option to purchase an aggregate of 350,000 additional ADS and additional warrants to purchase 650,070 ADSs.

The Underwriting Agreement provided that we, our directors and our executive officers will not issue, enter into any agreement to issue or announce the issuance or proposed issuance of any ADSs or ordinary shares or ordinary share equivalents, subject to certain exceptions, for a period of 90 days after the date of the offering. The Underwriting Agreement also contained representations, warranties, indemnification and other provisions customary for transactions of this nature.

In connection with the offering, the following office holders participated in the offering in the following amounts: (i) Kasbian Nuriel Chirich purchased 33,333 ADSs and 33,333 warrants to purchase 33,333 ADSs, (ii) Shai Yarkoni purchased 6,667 ADSs and 6,667 warrants to purchase 6,667 ADSs, (iii) Avraham Nahmias purchased 6,667 ADSs and 6,667 warrants to purchase 6,667 ADSs, and (iv) Eyal Leibovitz purchased 3,333 ADSs and 3,333 warrants to purchase 3,000 ADSs, and (v) Andrew Sabatier purchased 3,000 ADSs and 3,000 warrants to purchase 3,000 ADSs.

D. Exchange Controls

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

The ownership or voting of our ordinary shares by non-residents of Israel, except with respect to citizens of countries that are in a state of war with Israel, is not restricted in any way by our memorandum of association or amended and restated articles of association or by the laws of the State of Israel.

E. Taxation.

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our ordinary shares or ADSs or warrants (all referred to below as the 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, including Israeli, or other taxing jurisdiction.

Israeli Tax Considerations and Government Programs

The following is a summary of the material Israeli income tax laws applicable to us. This section also contains a discussion of material Israeli income tax consequences concerning the ownership and disposition of our Shares. This summary does not discuss all the aspects of Israeli income tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. To the extent that the discussion is based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion. This summary is based on laws and regulations in effect as of the date of this annual report and does not take into account possible future amendments which may be under consideration.

General corporate tax structure in Israel

Israeli companies are generally subject to corporate tax on their taxable income. As of 2018-2019, the corporate tax rate is 23% (in 2017, the corporate tax rate was 24%, in 2016, the corporate tax rate was 25% and in 2015, the corporate tax rate was 26.5%).

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

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." We believe that Collect Biotherapeutics is currently qualified as an Industrial Company within the meaning of the Industry Encouragement Law.

The Industry Encouragement Law defines an "Industrial Company" as a company 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. 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 of the cost of purchased a patent, rights to use a patent, and know-how, which are used for the development or advancement of the company, over an eight-year period, commencing on the year in which such rights were first exercised;
- Under limited conditions, an election to file consolidated tax returns with related Israeli Companies; And expenses related to a public offering are deductible in equal amounts over three years.

Eligibility for benefits under the Industry Encouragement Law is not contingent upon the approval of any governmental authority.

There can be no assurance that Collect Biotherapeutics will continue to qualify as an Industrial Company or that the benefits described above will be available 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 production facilities (or other eligible assets) by “Industrial Enterprises” (as defined under the Investment Law).

The Investment Law was significantly amended effective as of January 1, 2011, or the 2011 Amendment.

The 2011 Amendment introduced 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. Pursuant to the 2011 Amendment, 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 a specified development zone (Collect Biotherapeutics is not), in which case the rate will be 9%. Under the 2011 Amendment, the corporate tax rate is 16% and 9% in 2014 and thereafter.

Tax benefits are available under the 2011 Amendment to Industrial Enterprise, which are generally required to derive 25% or more of their business income from export in a market that have 14 million residents; or its revenues in a tax year from sales in one market does not exceed 75% percent of its entire sales in that tax year; or an industrial enterprise whose main activity is in the field of biotechnology or nanotechnology, and has been approved by the Israeli Innovation Authority and meet additional criteria stipulate in the amendment.

Dividends paid out of income attributed to a Preferred Enterprise are generally subject to withholding tax 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 (however, if afterward distributed to individuals or a non-Israeli company a withholding of 20%, or such lower rate as may be provided in an applicable tax treaty, will apply).

In December 2016, the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016 which includes Amendment 73 to the Law (“Amendment 73”) was published. According to Amendment 73, a preferred enterprise located in development area A will be subject to a tax rate of 7.5% instead of 9% effective from January 1, 2017 and thereafter (the tax rate applicable to preferred enterprises located in other areas remains at 16%).

The new tax tracks under the Amendment are as follows: Technological preferred enterprise - an enterprise for which total consolidated revenues of its parent company and all subsidiaries are less than NIS 10 billion. A technological preferred enterprise, as defined in the Law, which is located in the center of Israel will be subject to tax at a rate of 12% on profits deriving from intellectual property (in development area A - a tax rate of 7.5%). Special technological preferred enterprise - an enterprise for which total consolidated revenues of its parent company and all subsidiaries exceed NIS 10 billion. Such enterprise will be subject to tax at a rate of 6% on profits deriving from intellectual property, regardless of the enterprise’s geographical location.

The Amendment also prescribes special tax tracks for technological enterprises, which are subject to regulations that were published by the Minister of Finance on May 1, 2017.

Currently, Collect Biotherapeutics is in a loss position for tax purposes and therefore does not implement the tax benefits according to the Investment Law. However, we believe that once Collect Biotherapeutics will have taxable income, it will be eligible for a reduced corporate tax rate according to the Investment Law.

Taxation of our Israeli individual shareholders on receipt of dividends

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

As of January 1, 2013, an additional income tax at a rate of 2% is imposed on high earners whose annual income or gain exceeds NIS 810,720. As of January 2017, the tax rate will be 3% on high earners whose annual income or gain exceeds NIS 640,000.

A “substantial shareholder” is generally a person who alone, or together with his relative or another person who collaborates with him on a regular basis, holds, directly or indirectly, at least 10% of any of the “means of control” of the corporation. “Means of control” generally include the right to vote, receive profits, nominate a director or an officer, receive assets upon liquidation, or instruct someone who holds any of the aforesaid rights regarding the manner in which he or she is to exercise such right(s), and all regardless of the source of such right.

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

Taxation of Israeli Resident Corporations on Receipt of Dividends

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

Capital Gains Taxes Applicable to Israeli Resident Shareholders

The income tax rate applicable to real capital gain (capital gain less the effect of inflation) derived by an Israeli individual from the sale of shares which had been purchased after January 1, 2012, whether listed on a stock exchange or not, is 25%. However, if such shareholder is considered a “Substantial Shareholder” (as defined above) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%. As of January 1, 2013, an additional tax at a rate of 2% is imposed on high earners whose annual income or gains exceed NIS 810,720. As of January 2017, the tax rate will be 3% on high earners whose annual income or gain exceeds NIS 640,000.

Moreover, capital gains derived by a shareholder who is a dealer or trader in securities, or to whom such income is otherwise taxable as ordinary business income, are taxed in Israel at ordinary income rates (23% as of 2018 and up to 47% for individuals as of 2017).

Taxation of Non-Israeli Shareholders on Receipt of Dividends

Non-Israeli residents are generally subject to Israeli income tax on the receipt of dividends paid on our Shares at the rate of 25% or 30% if such recipient is a “substantial shareholder” at the time receiving the dividend or on any date in the 12 months preceding such date. If the Shares are held by a nominee company, the nominee company or the financial institution will withhold at the source a tax of 25% whether the recipient is a substantial shareholder or not. Otherwise, the withholding at the source will be 25% or 30% in accordance with the above, unless a lower tax rate is provided in a tax treaty between Israel and the shareholder’s country of residence.

A non-Israeli resident who receives dividends from which tax was withheld is generally exempt from the duty to file returns in Israel in respect of such income; provided such income was not derived from a business conducted in Israel by the taxpayer, and the taxpayer has no other taxable sources of income in Israel.

For example, under the Convention Between the Government of the United States of America and the Government of Israel with Respect to Taxes on Income (Tax Treaty between Israel and US), as amended, Israeli withholding tax on dividends paid to a U.S. resident for treaty purposes may not, in general, exceed 25%. Where the recipient is a U.S. corporation owning 10% or more of the voting shares of the paying corporation during the part of the paying corporation’s taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any) and the dividend is not paid from the profits of a Approved Enterprise, and not more than 25% of the gross income of the paying corporation consists of interest or dividends (other than interest derived from the conduct of banking, insurance, or financing business or interest received from subsidiary corporations, 50% or more of the outstanding shares of the voting stock of which is owned by the paying corporation at the time such dividends or interest is received) the Israeli tax withheld may not exceed 12.5%, subject to certain conditions. Subject to the mentioned conditions above, if the recipient is a US corporation, according to the Tax Treaty between Israel and US the Israeli tax withheld may not exceed 15% in the case of dividends paid out of the profits of an “Approved Enterprise”, subject to certain conditions.

Capital gains income taxes applicable to non-Israeli shareholders.

Non-Israeli resident shareholders are generally exempt from Israeli capital gains tax on any gains derived from the sale, exchange or disposition of our Shares, provided that such gains were not derived from a permanent establishment or business activity of such shareholders in Israel. However, non-Israeli corporations will not be entitled to the foregoing exemptions if Israeli residents (1) jointly have a controlling interest of more than 25% in such non-Israeli corporation or (2) are the beneficiaries of or are entitled to 25% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly.

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

Estate and gift tax

Israeli law presently does not impose estate or gift taxes.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR ISRAELI TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR SHARES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

U.S. Federal Income Tax Considerations

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

Subject to the limitations described in the next paragraph, the following discussion summarizes the material U.S. federal income tax consequences to a “U.S. Holder” arising from the purchase, ownership and disposition of the ordinary shares, ADSs and warrants. For this purpose, a “U.S. Holder” is a beneficial owner of ordinary shares or ADSs or warrants that is: (1) an individual citizen or resident of the United States, including an alien individual who is a lawful permanent resident of the United States or meets the substantial presence residency test under U.S. federal income tax laws; (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state therein, or the District of Columbia; (3) an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of source; (4) a trust if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust; and (5) a trust that has a valid election in effect to be treated as a U.S. person to the extent provided in U.S. Treasury regulations.

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

This discussion does not address all of the tax considerations that may be relevant to a particular U.S. Holder based on such holder's particular circumstances, or to U.S. Holders that are subject to special treatment under U.S. federal income tax law, including: (1) banks, life insurance companies, regulated investment companies, or other financial institutions or "financial services entities"; (2) brokers or dealers in securities or foreign currency; (3) persons who acquired our ordinary shares or ADSs or warrants in connection with employment or other performance of services; (4) U.S. Holders that are subject to the U.S. alternative minimum tax; (5) U.S. Holders that hold our ordinary shares or ADSs or warrants as a hedge or as part of a hedging, straddle, conversion or constructive sale transaction or other risk-reduction transaction for U.S. federal income tax purposes; (6) tax-exempt entities; (7) real estate investment trusts; (8) U.S. Holders that expatriate out of the United States or former long-term residents of the United States; or (9) U.S. Holders having a functional currency other than the U.S. dollar. This discussion does not address the U.S. federal income tax treatment of a U.S. Holder that owns, directly, indirectly or constructively, at any time, ordinary shares or ADSs or warrants representing 10% or more of our voting power or value. This discussion also does not address any U.S. state or local or non-U.S. tax considerations, any U.S. federal estate, gift, generation-skipping, transfer, or alternative minimum tax considerations, or any U.S. federal tax consequences other than U.S. federal income tax consequences.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our ordinary shares or ADSs or warrants, the tax treatment of such entity or arrangement treated as a partnership and each person treated as a partner thereof generally will depend upon the status and activities of the entity and such person. A holder that is treated as a partnership for U.S. federal income tax purposes should consult its own tax advisor regarding the U.S. federal income tax considerations applicable to it and its partners of the purchase, ownership and disposition of our ordinary shares or ADSs or warrants.

Each prospective investor is advised to consult his or her own tax adviser for the specific tax consequences to that investor of purchasing, holding or disposing of our ordinary shares or ADSs or warrants, including the effects of applicable state, local, foreign or other tax laws and possible changes in the tax laws.

Taxation of Dividends Paid on Ordinary Shares or ADSs

We do not intend to pay dividends in the foreseeable future. In the event that we do pay dividends, and subject to the discussion under the heading "Passive Foreign Investment Companies" below, a U.S. Holder will be required to include in gross income as ordinary income the amount of any distribution paid on ordinary shares or ADSs (including the amount of any Israeli tax withheld on the date of the distribution), to the extent that such distribution does not exceed our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. The amount of a distribution which exceeds our current and accumulated earnings and profits will be treated first as a non-taxable return of capital, reducing the U.S. Holder's tax basis for the ordinary shares or ADSs to the extent thereof, and then as capital gain. Corporate holders generally will not be allowed a deduction for dividends received.

In general, preferential tax rates for "qualified dividend income" and long-term capital gains are applicable for U.S. Holders that are individuals, estates or trusts. For this purpose, "qualified dividend income" means, inter alia, dividends received from a "qualified foreign corporation." A "qualified foreign corporation" is a corporation that is entitled to the benefits of a comprehensive tax treaty with the United States, which includes an exchange of information program. The IRS has stated that the Israel/U.S. Tax Treaty satisfies this requirement and we believe we are eligible for the benefits of that treaty.

In addition, our dividends will be qualified dividend income if our ordinary shares or ADSs are readily tradable on the Nasdaq Capital Market or another established securities market in the United States. Dividends will not qualify for the preferential rate if we are treated, in the year the dividend is paid or in the prior year, as a PFIC, as described below under "Passive Foreign Investment Companies". A U.S. Holder will not be entitled to the preferential rate: (1) if the U.S. Holder has not held our ordinary shares or ADSs for at least 61 days of the 121 day period beginning on the date which is 60 days before the ex-dividend date, or (2) to the extent the U.S. Holder is under an obligation to make related payments on substantially similar property. Any days during which the U.S. Holder has diminished its risk of loss on our ordinary shares or ADSs are not counted towards meeting the 61-day holding period. Finally, U.S. Holders who elect to treat the dividend income as "investment income" pursuant to Code section 163(d)(4) will not be eligible for the preferential rate of taxation.

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

Distributions paid by us will generally be foreign source income for U.S. foreign tax credit purposes and will generally be considered passive category income for such purposes. Subject to the limitations set forth in the Code, U.S. Holders may elect to claim a foreign tax credit against their U.S. federal income tax liability for Israeli income tax withheld from distributions received in respect of the ordinary shares or ADSs. The rules relating to the determination of the U.S. foreign tax credit are complex, and U.S. Holders should consult with their own tax advisors to determine whether, and to what extent, they are entitled to such credit. U.S. Holders that do not elect to claim a foreign tax credit may instead claim a deduction for Israeli income taxes withheld, provided such U.S. Holders itemize their deductions.

Taxation of the Disposition of Ordinary Shares or ADSs or Warrants

Subject to the discussion under the heading “Passive Foreign Investment Companies” below, upon the sale, exchange or other taxable disposition of our ordinary shares or ADSs or warrants, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between such U.S. Holder’s tax basis for the ordinary shares or ADSs or warrants in U.S. dollars and the amount realized on the disposition in U.S. dollars (or its U.S. dollar equivalent determined by reference to the spot rate of exchange on the date of disposition, if the amount realized is denominated in a foreign currency). The gain or loss realized on the sale, exchange or other disposition of ordinary shares or ADSs or warrants will be long-term capital gain or loss if the U.S. Holder has a holding period of more than one year at the time of the disposition. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of receiving currency other than U.S. dollars upon the disposition of their ordinary shares.

Gain realized by a U.S. Holder on a sale, exchange or other disposition of ordinary shares or ADSs or warrants will generally be treated as U.S. source income for U.S. foreign tax credit purposes. A loss realized by a U.S. Holder on the sale, exchange or other disposition of ordinary shares or ADSs or warrants is generally allocated to U.S. source income. The deductibility of a loss realized on the sale, exchange or other disposition of ordinary shares or ADSs or warrants is subject to limitations.

Exercise or Lapse of a Warrant

A U.S. Holder generally will not recognize gain or loss upon the exercise of a warrant for cash. An ordinary share or ADS acquired pursuant to the exercise of a warrant for cash generally will have a tax basis equal to the U.S. Holder’s tax basis in the warrant, increased by the amount paid to exercise the warrant. Subject to the discussion under the heading “Passive Foreign Investment Companies” below, the holding period of such share or ADS generally begins on the day after the date of exercise of the warrant and will not include the period during which the U.S. Holder held the warrant. If a warrant is allowed to lapse unexercised, a U.S. Holder generally will recognize a capital loss equal to such holder’s tax basis in the warrant. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of the exercise of a warrant, including with respect to whether the exercise is a taxable event, and their holding period and tax basis in the ordinary shares or ADSs received.

Passive Foreign Investment Companies

Special U.S. federal income tax laws apply to U.S. taxpayers who owns shares of a corporation that is a PFIC. We will be treated as a PFIC for U.S. federal income tax purposes for any taxable year in which either:

- 75% or more of our gross income (including our pro rata share of gross income for any company in which we are considered to own 25% or more of the shares by value) is passive; or
- at least 50% of our assets, averaged quarterly over the year (including our pro rata share of the assets of any company in which we are considered to own 25% or more of the shares by value) and generally determined based upon value are held for the production of, or produce, passive income.

For this purpose, passive income generally consists of dividends, interest, rents, royalties, annuities and income from certain commodities transactions and from notional principal contracts. Cash is treated as generating passive income.

A foreign corporation’s PFIC status is an annual determination that is based on tests that are factual in nature, and our status for any year will depend on our income, assets, and activities for such year. We believe that we were a PFIC for our 2018 taxable year. Because the PFIC determination is highly fact intensive, there can be no assurance that we will not be a PFIC for 2019 or for any other taxable year. U.S. Holders who hold ordinary shares or ADSs or warrants during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC, subject to specified exceptions for U.S. Holders who made a “qualified electing fund” or “QEF”, or “mark-to-market” election with respect to our ordinary shares or ADSs. Upon request, we expect to provide the information necessary for U.S. Holders to make QEF elections if we are classified as a PFIC.

If we currently are or become a PFIC, each U.S. Holder who has not elected to treat us as a qualified electing fund by making a “QEF election”, or who has not elected to mark the shares to market (as discussed below), will be subject to special rules with respect to (i) any “excess distribution” (generally, the portion of any distributions received by the non-electing U.S. Holder on the ordinary shares or ADSs or warrants in a taxable year in excess of 125% of the average annual distributions received by the non-electing U.S. Holder in the three preceding taxable years, or, if shorter, the non-electing U.S. Holder’s holding period for the ordinary shares or ADSs or warrants), and (ii) any gain realized on the sale or other disposition of such ordinary shares or ADSs or warrants. Under these rules:

- the excess distribution or gain would be allocated ratably over the non-electing U.S. Holder’s holding period for such ordinary shares or ADSs or warrants;
- the amount allocated to the current taxable year and any year prior to us becoming a PFIC would be taxed as ordinary income; and
- the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year.

In addition, when shares of a PFIC are acquired by reason of death from a decedent that was a U.S. Holder, the tax basis of such shares would not receive a step-up to fair market value as of the date of the decedent’s death, but instead would be equal to the decedent’s basis if lower, unless all gain were recognized by the decedent. Indirect investments in a PFIC may also be subject to these special U.S. federal income tax rules.

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

In addition, the PFIC rules described above would not apply if we were a PFIC and a U.S. Holder made a mark-to-market election with respect to our ordinary shares or ADSs. A U.S. Holder of our ordinary shares or ADSs which are regularly traded on a qualifying exchange, including Nasdaq, can elect to mark the ordinary shares or ADSs to market annually, recognizing as ordinary income or loss each year an amount equal to the difference as of the close of the taxable year between the fair market value of the ordinary shares or ADSs and the U.S. Holder’s adjusted tax basis in the ordinary shares or ADSs or warrants. Losses are allowed only to the extent of net mark-to-market gain previously included income by the U.S. Holder under the election for prior taxable years. Thus, a U.S. Holder may recognize taxable income without receiving any cash to pay its tax liability with respect to such income. A U.S. Holder’s tax basis in our ordinary shares or ADSs would be adjusted to reflect any such income or loss amount. Gain realized on the sale, exchange or other disposition of our ordinary shares or ADSs would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of our ordinary shares or ADSs would be treated as ordinary loss to the extent that such loss does not exceed the net mark-to-market gains previously included in income by the U.S. Holder, and any loss in excess of such amount will be treated as capital loss. Amounts treated as ordinary income will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains. A U.S. Holder may not make a mark-to-market election with respect to our warrants.

U.S. Holders who do not make a timely QEF election or a mark-to-market election, and who hold our ordinary shares or ADSs or warrants during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC. U.S. Holders are strongly urged to consult their tax advisors about the PFIC rules, including tax return filing requirements and the eligibility, manner, and consequences to them of making a QEF or mark-to-market election with respect to our ordinary shares or ADSs in the event that we are a PFIC.

Tax on Investment Income

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

Tax Consequences for Non-U.S. Holders of Ordinary Shares or ADSs or Warrants

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

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

In general, non-U.S. Holders will not be subject to backup withholding with respect to the payment of dividends on our ordinary shares or ADSs or warrants if payment is made through a paying agent or office of a foreign broker outside the United States. However, if payment is made in the United States or by a U.S. related person, non-U.S. Holders may be subject to backup withholding, unless the non-U.S. Holder provides an applicable IRS Form W-8 (or a substantially similar form) certifying its foreign status, or otherwise establishes an exemption.

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

Information Reporting and Withholding

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

A U.S. Holder with interests in "specified foreign financial assets" (including, among other assets, our ordinary shares or ADSs or warrants, unless such ordinary shares or ADSs or warrants are held on such U.S. Holder's behalf through a financial institution) may be required to file an information report with the IRS if the aggregate value of all such assets exceeds \$50,000 on the last day of the taxable year or \$75,000 at any time during the taxable year (or such higher dollar amount as may be prescribed by applicable IRS guidance). U.S. Holders should consult their tax advisors as to the possible obligation to file such information reports in light of their particular circumstances.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to certain information reporting requirements of the Exchange Act, applicable to foreign private issuers and under those requirements will file reports with the SEC. The SEC maintains an internet site at <http://www.sec.gov> that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. We maintain a corporate website www.collect.co. Information contained on, or that can be accessed through, our website and the other websites referenced above do not constitute a part of this annual report on Form 20-F. We have included these website addresses in this annual report on Form 20-F solely as inactive textual references.

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and may submit to the SEC, on a Form 6-K, unaudited quarterly financial information.

I. Subsidiary Information.

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the ordinary course of our operations, we are exposed to certain market risks, primarily changes in foreign currency exchange rates and interest rates.

Quantitative and Qualitative Disclosure 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, results of operations or cash flows due to adverse changes in financial market prices and rates, including interest rates and foreign exchange rates, of financial instruments. Our market risk exposure is primarily a result of interest rates and foreign currency exchange rates.

Interest Rate Risk

Following the date of this annual report, we do not anticipate undertaking any significant long-term borrowings. At present, our investments consist primarily of cash and cash equivalents and financial assets at fair value. Following the date of this annual report, we may invest in investment-grade marketable securities with maturities of up to three years, including commercial paper, money market funds, and government/non-government debt securities. The primary objective of our investment activities is to preserve principal while maximizing the income that we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any. We manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities, if any, of our investments to date, their carrying value has always approximated their fair value. If we decide to invest in investments other than cash and cash equivalents, it will be our policy to hold such investments to maturity in order to limit our exposure to interest rate fluctuations.

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the NIS, our functional and reporting currency, mainly against the U.S. dollar. Although the NIS is currently our functional currency, a small portion of our expenses are denominated in U.S. dollars. Our U.S. dollar expenses consist principally of payments made to sub-contractors and consultants for clinical trials and other research and development activities as well as payments made to purchase new equipment. We anticipate that our expenses in U.S. dollar will increase in the future. If the NIS fluctuates significantly against the U.S. dollar, it may have a negative impact on our results of operations. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition.

To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities.

Not applicable.

B. Warrants and rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares

Fees and Expenses

Persons depositing or withdrawing ordinary shares or ADS holders must pay:

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

\$.05 (or less) per ADS

A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the ordinary shares had been deposited for issuance of ADSs

\$.05 (or less) per ADS per calendar year

Registration or transfer fees

Expenses of the depositary

Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or ordinary shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes

Any charges incurred by the depositary or its agents for servicing the deposited securities

For:

Issuance of ADSs, including issuances resulting from a distribution of ordinary shares or rights or other property

Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates

Any cash distribution to ADS holders

Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders

Depositary services

Transfer and registration of ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw ordinary shares

Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement); converting foreign currency to U.S. dollars

As necessary

As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

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

There are no material modifications to the rights of security holders.

Use of Proceeds

Initial Public Offering

The effective date of the registration statement (File no. 333-212432) for our initial U.S public offering of our ADSs and warrants, was July 28, 2016. The offering with respect to our ADSs and warrants commenced on July 28, 2016 and was closed on August 3, 2016. H.C. Wainwright & Co., LLC was the book-running manager for the offering. We registered 1,292,308 ADSs, each representing 20 of our ordinary shares, and public warrants to purchase up to 969,231 ADSs, and granted the underwriters a 45-day option to purchase up to an additional 193,846 ADSs and/or warrants to purchase an additional 145,385 ADSs, at the public offering price, less underwriting discount, to cover over-allotments, if any. The over-allotment option was partially exercised by the underwriters for the purchase of warrants to purchase 65,890 ADSs.

The gross proceeds received by us from this offering were approximately \$8.4 million prior to deducting underwriting discounts, commissions and other estimated offering expenses. Under the terms of the offering, we incurred aggregate underwriting discounts and commissions of approximately \$0.6 million and expenses of approximately \$0.2 million in connection with the offering, resulting in net proceeds to us of approximately \$7.6 million. None of the expenses was paid directly or indirectly to any director, officer, general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates

The primary purposes of this offering were to fund our Phase I/II single arm, open label clinical trial, perform a pivotal study, develop our ApoTainer selection kit product, advance the development of our technology platform for additional indications and for general research activities as well as for working capital and other general corporate purposes.

As of March 12, 2019, we have used approximately \$3.5 million of the net proceeds of this offering for on-going R&D and clinical research, approximately \$4.1 million to working capital and any other purposes. Accordingly, all of the net proceeds from this offering have been used.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2018, or the Evaluation Date. Based on such evaluation, those officers have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the Exchange Act and that such information is accumulated and communicated to management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

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

Our management, including our CEO, and our CFO, are responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and asset dispositions;
- provide reasonable assurance that transactions are recorded as necessary to permit the preparation of our financial statements in accordance with generally accepted accounting principles;
- provide reasonable assurance that receipts and expenditures are made only in accordance with authorizations of our management and board of directors (as appropriate); and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

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

Under the supervision and with the participation of our management, including our CEO, and our CFO, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the framework for Internal Control-Integrated Framework set forth by The Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013).

Based on our assessment and this framework, our management concluded that our internal control over financial reporting were effective as of December 31, 2018.

(c) Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption for emerging growth companies provided in the JOBS Act.

(d) Changes in Internal Control over Financial Reporting

During the year ended December 31, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that each of the following two members of our audit committee, Jonathan Burgin and Abraham Nahmias, is an audit committee financial expert, as defined under the rules under the Exchange Act, and is independent in accordance with applicable Exchange Act rules and the Nasdaq Capital Market rules.

ITEM 16B. CODE OF ETHICS

Our board of directors has adopted a Code of Ethics which became effective upon the listing of our ADSs and warrants on the Nasdaq Capital Market 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 Item 16B of Form 20-F promulgated by the SEC. The full text of the Code of Ethics is posted on our website at www.collect.co. Information contained on, or that can be accessed through, our website does not constitute a part of this a part of this annual report on Form 20-F and is not incorporated by reference herein. If we make any amendment to the Code of 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. We have not granted any waivers under our Code of Business Conduct and Ethics.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, an independent registered public accounting firm, has served as our principal independent registered public accounting firm for each of the two years ended December 31, 2018 and 2017.

The following table provides information regarding fees paid by us to Kost Forer Gabbay & Kasierer and/or other member firms of Ernst & Young Global for all services, including audit services, for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
(in thousands)		
Audit fees ⁽¹⁾	\$ 74	74
Audit-related fees	40	34
Tax fees ⁽²⁾	14	6
All other fees	-	-
Total	<u>\$ 128</u>	<u>114</u>

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

(2) Includes professional fees related to tax returns.

Pre-Approval of Auditors' Compensation

Our audit committee has a pre-approval policy for the engagement of our independent registered public accounting firm to perform certain audit and non-audit services. Pursuant to this policy, which is designed to assure that such engagements do not impair the independence of our auditors, the audit committee pre-approves annually a catalog of specific audit and non-audit services in the categories of audit services, audit-related services and tax services that may be performed by our independent registered public accounting firm. If a type of service, that is to be provided by our auditors, has not received such general pre-approval, it will require specific pre-approval by our audit committee. The policy prohibits retention of the independent registered public accounting firm to perform the prohibited non-audit functions defined in applicable SEC rules.

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

Not applicable.

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

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

The Sarbanes-Oxley Act, as well as related rules subsequently implemented by the SEC, require foreign private issuers, such as us, to comply with various corporate governance practices. In addition, we are required to comply with the Nasdaq Capital Market rules. Under those rules, we may elect to follow certain corporate governance practices permitted under the Companies Law in lieu of compliance with corresponding corporate governance requirements otherwise imposed by the Nasdaq Capital Market rules for U.S. domestic issuers.

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

Distribution of certain reports to shareholders. As opposed to the listing rules of the Nasdaq, which require listed issuers to make certain reports, such as annual reports, interim reports and quarterly reports, available to shareholders in one of a number of specific manners, Israeli law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders, but to make such reports available through a public website. In addition to making such reports available on a public website, we plan to make our audited financial statements available to our shareholders at our offices and will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

Nomination of directors. With the exception of our external directors and directors elected by our board of directors due to vacancy, our directors are elected by an annual meeting of our shareholders to hold office until the next annual meeting following his or her election. See "Board Practices." The nominations for directors, which are presented to our shareholders by our board of directors, are generally made by the board of directors itself, in accordance with the provisions of our articles of association and the Companies Law. One or more shareholders of a company holding at least 1% of the voting power of the company may nominate a currently serving external director for an additional three year term. Nominations need not be made by a nominating committee of our board of directors consisting solely of independent directors or by independent directors constituting a majority of independent directors, as required under the listing rules of the Nasdaq.

Compensation of officers. We follow the provisions of the Companies Law with respect to matters in connection with the composition and responsibilities of our compensation committee, office holder compensation and any required approval by the shareholders of such compensation. Israeli law and our articles of association do not require that the independent members of our board of directors, or a compensation committee composed solely of independent members of our board of directors, determine an executive officer's compensation, as is generally required under the listing rules of the Nasdaq with respect to the Chief Executive Officer and all other executive officers of a company. However, Israeli law and our articles of association do require that our audit and compensation committees each contain two external directors (as defined in the Companies Law. See "Board Practices — External Directors."). In addition, Israeli law requires that additional members of the compensation committee and the external directors be compensated equally. Our compensation committee has been established and conducts itself in accordance with the provisions governing the composition of and the responsibilities of a compensation committee as set forth in the Companies Law. Furthermore, compensation of office holders is determined and approved by our compensation committee, and in general, by our board of directors as well, and in certain circumstances by our shareholders, as detailed below under the caption "— Shareholder Approval." Thus, we will seek shareholder approval for all corporate actions with respect to office holder compensation (including the compensation required to be approved for our Chief Executive Officer) requiring such approval under the requirements of the Companies Law, including seeking prior approval of the shareholders for the compensation policy and for certain office holder compensation, rather than seeking approval for such corporate actions in accordance with listing rules of the Nasdaq. See "— Compensation Committee and Compensation Policy" below.

Compensation Committee. Pursuant to the Companies Law, we established a compensation committee as detailed above under “Compensation Committee and Compensation Policy”. Our board of directors has affirmatively determined that each member of our compensation committee qualifies as “independent” under applicable the Nasdaq Capital Market and SEC rules.

Independent directors. Israeli law does not require that a majority of the directors serving on our board of directors be “independent,” as defined under the Nasdaq Capital Market Listing Rule 5605(a)(2), but rather requires we have at least two external directors who meet the requirements of the Companies Law, as described below under “Board Practices — External Directors.” We are required, however, to ensure that all members of our audit committee are “independent” under the Companies Law and the applicable the Nasdaq Capital Market and SEC criteria for independence, and under Israeli law, the audit committee and compensation committee must each include all external directors then serving on our board of directors. We must also ensure that a majority of the members of our audit committee are “unaffiliated directors” as defined in the Companies Law, as described under the caption “— Audit Committee.” Our board of directors has affirmatively determined that each of: Michael Berelowitz, Jonathan Burgin, Ruhama Avraham, David Braun and Abraham Nahmias qualifies as “independent” under the Nasdaq Capital Market independence standards.

Shareholder approval. We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Companies Law, rather than seeking approval for corporate actions in accordance with the Nasdaq Capital Market Listing Rule 5635. In particular, under the Nasdaq Capital Market rule, shareholder approval is generally required for: (i) an acquisition of shares or assets of another company that involves the issuance of 20% or more of the acquirer’s shares or voting rights or if a director, officer or 5% shareholder has greater than a 5% interest in the target company or the consideration to be received; (ii) the issuance of shares leading to a change of control; (iii) adoption or material amendment of equity compensation arrangements; and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) of a listed company via a private placement (or via sales by directors, officers or 5% shareholders) if such equity is issued (or sold) at below the greater of the book or market value of shares. By contrast, under the Companies Law, shareholder approval is required for, among other things: (a) transactions with directors concerning the terms of their service or indemnification, exemption and insurance for their service (or for any other position that they may hold at a company), for which approvals of the compensation committee, board of directors and shareholders are all required, (b) extraordinary transactions with controlling shareholders of publicly held companies, which require the special approval described under “Disclosure of personal interests of controlling shareholders and approval of certain transactions,” (c) terms of office and employment or other engagement of our controlling shareholder, if any, or such controlling shareholder’s relative, which require the special approval described under “Disclosure of personal interests of controlling shareholders and approval of certain transactions,” (d) approval of transactions with company’s Chief Executive Officer with respect to his or her compensation, whether in accordance with the approved compensation policy of the company or not in accordance with the approved compensation policy of the company, or transactions with officers of the company not in accordance with the approved compensation policy, and (e) approval of the compensation policy of the company for office holders. In addition, under the Companies Law, a merger requires approval of the shareholders of each of the merging companies.

Other than the foregoing home country practices, we otherwise comply with the rules generally applicable to U.S. domestic companies listed on The Nasdaq Capital Market. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other the Nasdaq Capital Market corporate governance rules. Following our home country corporate governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the Nasdaq Capital Market may provide less protection to you than what is accorded to investors under the listing rules of the Nasdaq applicable to domestic U.S. issuers.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to provide financial statements and related information pursuant to Item 18.

ITEM 18. FINANCIAL STATEMENTS

The consolidated financial statements and the related notes required by this Item are included in this annual report on Form 20-F beginning on page F-1.

ITEM 19. EXHIBITS.

Exhibit No.	Exhibit Description
1.1	<u>Articles of Association of Collect Biotechnology Ltd. (unofficial English translation from Hebrew original) (included as Exhibit 3.1 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on July 7, 2016, and incorporated herein by reference).</u>
1.2	<u>Certificate of Name Change of Collect Biotechnology Ltd. (unofficial English translation from Hebrew original) (included as Exhibit 3.2 to our Registration Statement on Form F-1/A as filed with the Securities and Exchange Commission on July 25, 2016, and incorporated herein by reference).</u>
2.1	<u>Form of Deposit Agreement between Collect Biotechnology Ltd., The Bank of New York Mellon as Depositary, and owners and holders from time to time of ADSs issued thereunder (included as Exhibit 4.1 to our Registration Statement on Form F-1/A as filed with the Securities and Exchange Commission on July 26, 2016, and incorporated herein by reference).</u>
2.2	<u>Specimen American Depositary Receipt (included in Exhibit 2.1)</u>
2.3	<u>Form of Warrant Agent Agreement (included as Exhibit 4.3 to our Registration Statement on Form F-1/A as filed with the Securities and Exchange Commission on July 26, 2016, and incorporated herein by reference).</u>

Exhibit No.	Exhibit Description
2.4	<u>Form of Underwriters' Warrant (included as Exhibit 4.4 to our Registration Statement on Form F-1/A as filed with the Securities and Exchange Commission on July 26, 2016, and incorporated herein by reference).</u>
4.1	<u>Founders Agreement dated June 1, 2011 between Kasbian Nuriel Chirich, Dr. Shai Yarkoni, and Dr. Nadir Askenasy (included as Exhibit 10.1 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on July 7, 2016, and incorporated herein by reference).</u>
4.2	<u>Chairman of the Board Agreement dated April 30, 2013 between Collect Biotechnology Ltd. and Kasbian Nuriel Chirich (unofficial English translation from Hebrew original) (included as Exhibit 10.2 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on July 7, 2016, and incorporated herein by reference).</u>
4.3	<u>Employment Agreement dated April 30, 2013 between Collect Biotechnology Ltd. and Dr. Shai Yarkoni (unofficial English translation from Hebrew original) (included as Exhibit 10.3 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on July 7, 2016, and incorporated herein by reference).</u>
4.4	<u>Collect Biotechnology Ltd. 2014 Global Incentive Option Scheme (included as Exhibit 10.6 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on July 7, 2016, and incorporated herein by reference).</u>
4.5	<u>Amended and Restated Compensation Policy (included as Exhibit A to Exhibit 99.1 of our Report on Form 6-K as filed with the Securities and Exchange Commission on May 24, 2018, and incorporated herein by reference).</u>
4.6	<u>Amendment to Dr. Shai Yarkoni Employment Agreement dated July 24, 2016 between Collect Biotherapeutics Ltd. and Dr. Shai Yarkoni (unofficial English translation from Hebrew original) (included as Exhibit 10.8 to our Registration Statement on Form F-1/A as filed with the Securities and Exchange Commission on July 25, 2016, and incorporated herein by reference).</u>
4.7	<u>Amendment to Kasbian Nuriel Chirich Employment Agreement dated July 24, 2016 between Collect Biotherapeutics Ltd. and Kasbian Nuriel Chirich (unofficial English translation from Hebrew original) (included as Exhibit 10.9 to our Registration Statement on Form F-1/A as filed with the Securities and Exchange Commission on July 25, 2016, and incorporated herein by reference).</u>
4.8	<u>Form Indemnification and Release Instrument (included as Exhibit B to Exhibit 99.1 of our Report on Form 6-K as filed with the Securities and Exchange Commission on May 24, 2018, and incorporated herein by reference).</u>
4.9	<u>Form of Underwriting Agreement (included as Exhibit 1.1 to our Registration Statement on Form F-1/A as filed with the Securities and Exchange Commission on July 22, 2016, and incorporated herein by reference).</u>
4.10	<u>Form of Securities Purchase Agreement for the September 2017 Financing (included as Exhibit 10.1 to our Report on Form 6-K as filed with the Securities and Exchange Commission on September 8, 2017, and incorporated herein reference).</u>

Exhibit No.	Exhibit Description
4.11	Form of Warrant for the September 2017 Financing (included as Exhibit 10.2 to our Report on Form 6-K as filed with the Securities and Exchange Commission on September 8, 2017, and incorporated herein reference).
4.12	Form of Securities Purchase Agreement for the January 2018 Financing (included as Exhibit 10.1 to our Report on Form 6-K as filed with the Securities and Exchange Commission on January 31, 2018, and incorporated herein reference).
4.13	Form of Warrant for the January 2018 Financing (included as Exhibit 10.2 to our Report on Form 6-K as filed with the Securities and Exchange Commission on January 31, 2018, and incorporated herein reference).
4.14	Form of Underwriting Agreement (incorporated by reference to Exhibit 1.1 of the Registration Statement on Form F-1/A filed with the Securities and exchange Commission on February 7, 2019).
4.15	Form of Warrant Agent Agreement dated between Collect Biotechnology Ltd. and Computershare Inc., as warrant agent, including the form of Warrant (incorporated by reference to Exhibit 4.6 of the Registration Statement on Form F-1 filed with the Securities and exchange Commission on February 7, 2019).
4.16	Form of Pre-Funded Warrant Agent Agreement between Collect Biotechnology Ltd. and Computershare Inc., as warrant agent, including the form of Pre-funded Warrant (incorporated by reference to Exhibit 4.7 of the Registration Statement on Form F-1 filed with the Securities and exchange Commission on February 7, 2019).
8.1	Subsidiaries of Collect Biotechnology Ltd.*
12.1	Certification of the Chief Executive Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934.*
12.2	Certification of the Chief Financial Officer pursuant to rule 13a-14(a) of the Securities Exchange Act of 1934.*
13.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, furnished herewith.*
13.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, furnished herewith.*
15.1	Consent of Kost Forer Gabbay & Kasierer, Certified Public Accountant (Isr.), a member of Ernst & Young Israel.*
101	The following financial information from Collect Biotechnology Ltd.'s Annual Report on Form 20-F for the year ended December 31, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Statements of Changes in Equity (iv) the Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements.*

* Filed Herewith

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 Form 20-F filed on its behalf.

CELLECT BIOTECHNOLOGY LTD.

By: /s/ Dr. Shai Yarkoni
Dr. Shai Yarkoni
Chief Executive Officer

Date: March 18, 2019

CELLECT BIOTECHNOLOGY LTD
AND ITS SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2018

NIS IN THOUSANDS

INDEX

	<u>Page</u>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Comprehensive Loss</u>	F-4
<u>Statements of Changes in Equity</u>	F-5
<u>Consolidated Statements of Cash Flows</u>	F-6 – F-7
<u>Notes to Consolidated Financial Statements</u>	F-8 – F-32



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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

**To the Shareholders and
Board of Directors of**

Collect Biotechnology Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Collect Biotechnology Ltd. and its subsidiaries (the “Company”) as of December 31, 2018 and 2017, the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

The Company’s Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1b to the consolidated financial statements, the Company incurred losses totaling NIS 20,113 thousand and negative cash flow from operating activity totaling NIS 23,635 during the year ended December 31, 2018. Additionally, the Company has not yet generated revenues from its operations and is dependent on external sources for financing its operations. Due to these conditions, the Company has stated that substantial doubt exists about the Company’s ability to continue as a going concern. Management’s evaluation of the events and conditions and management’s plans regarding these matters are also described in Note 1b. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 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.

We have served as the Company’s auditor since 2011
Tel-Aviv, Israel
March 18, 2019

/s/ Kost Forer Gabbay & Kasierer
KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

CONSOLIDATED BALANCE SHEETS

In thousands, except number of shares data

	December 31,		Convenience translation (Note 2d)
	2017	2018	December 31,
	N I S		2018
			U.S. dollars
CURRENT ASSETS:			
Cash and cash equivalents	13,734	17,809	4,752
Marketable securities	13,999	-	-
Other receivables	818	816	218
	<u>28,551</u>	<u>18,625</u>	<u>4,970</u>
LONG-TERM ASSETS:			
Restricted cash	305	337	90
Other Long term receivables	173	132	35
Property, plant and equipment, net	1,344	1,544	412
	<u>1,822</u>	<u>2,013</u>	<u>537</u>
	<u>30,373</u>	<u>20,638</u>	<u>5,507</u>
CURRENT LIABILITIES:			
Trade payables	1,703	887	237
Other payables	2,396	4,012	1,070
	<u>4,099</u>	<u>4,899</u>	<u>1,307</u>
NON CURRENT LIABILITIES:			
Warrants to ADS	7,422	1,816	485
CONTINGENT LIABILITIES AND COMMITMENTS			
SHAREHOLDERS' EQUITY:			
Ordinary shares of no par value:			
Authorized: 500,000,000 shares at December 31, 2017, and 2018, Issued and outstanding: 120,185,659*) and 130,414,799*) shares as of December 31, 2017 and 2018, respectively.	-	-	-
Additional Paid In Capital	82,839	95,085	25,370
Share-based payments	9,381	12,319	3,287
Treasury shares	(9,425)	(9,425)	(2,515)
Accumulated deficit	(63,943)	(84,056)	(22,427)
	<u>18,852</u>	<u>13,923</u>	<u>3,715</u>
	<u>30,373</u>	<u>20,638</u>	<u>5,507</u>

*) Net of 2,641,693 treasury shares of the Company, held by the Company.

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

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands, except number of shares data

	Year ended December 31,			Convenience translation (Note 2d)
	2016	2017	2018	Year ended December 31, 2018
	N I S			U.S. dollars
Research and development expenses, net	8,256	11,503	13,513	3,605
General and administrative expenses	7,968	12,930	15,734	4,198
Other Income	(280)	-	-	-
Total operating expenses	15,944	24,433	29,247	7,803
Operating loss	15,944	24,433	29,247	7,803
Financial income	(660)	(101)	(9,154)	(2,442)
Financial expenses	33	3,892	20	6
Total Comprehensive loss	15,317	28,224	20,113	5,367
Loss per share				
Basic and diluted loss per share	0.168	0.252	0.155	0.041
Basic and diluted loss per ADS	3.36	5.04	3.11	0.82
Weighted average number of shares outstanding used to compute basic and diluted loss per share	91,128,516	111,968,663	129,426,091	129,426,091

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

STATEMENTS OF CHANGES IN EQUITY

In thousands, except number of shares data

	Share capital	Additional paid in capital	Treasury shares	Share based payments	Accumulated deficit	Total equity
N I S						
<u>Balance as of January 1, 2016</u>	-	36,725	(9,425)	3,603	(20,402)	10,501
Issuance of share capital net of issue costs (see Note 11a1)	-	30,682	-	1,062	-	31,744
Share-based payment	-	-	-	1,552	-	1,552
Exercise of share options	-	7	-	-	-	7
Total comprehensive loss	-	-	-	-	(15,317)	(15,317)
<u>Balance as of December 31, 2016</u>	-	67,414	(9,425)	6,217	(35,719)	28,487
Issuance of ADS net of issue costs (see Note 11a7)	-	11,693	-	80	-	11,773
Share-based payment	-	642	-	4,742	-	5,384
Exercise of share options and warrants	-	2,470	-	(1,038)	-	1,432
Expiration of share options	-	620	-	(620)	-	-
Total comprehensive loss	-	-	-	-	(28,224)	(28,224)
<u>Balance as of December 31, 2017</u>	-	82,839	(9,425)	9,381	(63,943)	18,852
Issuance of ADS net of issue costs (see Note 11a7)	-	10,024	-	223	-	10,247
Share-based payment	-	186	-	4,351	-	4,537
Exercise of share options and warrants	-	753	-	(353)	-	400
Expiration of share options	-	1,283	-	(1,283)	-	-
Total comprehensive loss	-	-	-	-	(20,113)	(20,113)
Balance as of December 31, 201	-	95,085	(9,425)	12,319	(84,056)	13,923
convenience translation in U.S. dollars (see Note 2d)	-	25,370	(2,515)	3,287	(22,427)	3,715

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands, except number of shares data

	Year ended December 31,			Convenience translation (Note 2d)
	2016	2017	2018	Year ended December 31, 2018
	N I S			U.S. dollars
Cash Flows from Operating Activities:				
Total Comprehensive Loss	(15,317)	(28,224)	(20,113)	(5,367)
Adjustments to reconcile net loss to net cash used in operating activities:				
Adjustments to profit and loss items:				
Exchange rate difference	134	532	(1,297)	(345)
Loss (Gain) from revaluation of financial assets presented at fair value through profit and loss	(106)	139	(397)	(106)
Depreciation and capital loss from sale of property, plant and equipment	350	372	459	122
Share-based payment	1,552	5,384	4,537	1,210
Changes in fair value of Traded and Non Traded Warrants To ADS	(1,235)	3,003	(7,719)	(2,059)
	695	9,430	(4,417)	(1,178)
Changes in asset and liability items:				
Decrease (increase) in other receivables	(1,049)	470	43	12
Increase in other payables	1,259	407	798	213
	210	877	841	225
Cash paid and received during the year for:				
Interest received	-	147	54	14
Net cash used in operating activities	(14,412)	(17,770)	(23,635)	(6,306)
Cash Flows from Investing Activities:				
Proceeds received from the sale of fixed assets	95	-	-	-
Short term deposits, net	(19,530)	19,530	387	103
Restricted deposit	(120)	(165)	(22)	(6)
Marketable securities measured at fair value through profit and loss, net	2,808	(9,008)	13,999	3,735
Purchase of property, plant and equipment	(1,265)	(266)	(656)	(175)
Net cash provided by (used in) investing activities	(18,012)	10,091	13,708	3,657

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands, except number of shares data

	Year ended December 31,			Convenience translation (Note 2d)
	2016	2017	2018	Year ended December 31,
	N I S			2018 U.S. dollars
<u>Cash Flows from Financing Activities:</u>				
Exercise of warrants and stock options into shares	7	1,432	399	106
Issuance of share capital and warrants, net of issue costs (see note 11)	34,917	14,381	12,360	3,299
Net cash provided by financing activities	34,924	15,813	12,759	3,405
<u>Exchange differences on balances of cash and cash equivalents</u>	(134)	(679)	1,243	332
<u>Increase in cash and cash equivalents</u>	2,366	7,455	4,075	1,088
<u>Balance of cash and cash equivalents at the beginning of the year</u>	3,913	6,279	13,734	3,664
<u>Balance of cash and cash equivalents at the end of the year</u>	6,279	13,734	17,809	4,752
<u>(a) Non-cash activities:</u>				
Purchase of property, plant and equipment	58	77	3	1
Issuance costs	-	127	-	-

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data****NOTE 1:- GENERAL**

- a. Cellect Biotechnology Ltd. (formerly Cellect Biomed Ltd.) (the “Company” or “Cellect”) is incorporated in Israel. Cellect and its subsidiary, Cellect Biotherapeutics Ltd. (the “Subsidiary”) are engaged in the development of an innovative, unique technology that enables the biological filtering and commercialization of stem cells. On May 25, 2018 the Company established a US subsidiary, Cellect Biotech Inc. Cellect’s American Depository Shares (“ADSs”) and certain warrants to purchase ADSs are listed for trading on the Nasdaq Capital Market. Each ADS represents 20 ordinary shares.

On September 5, 2017, the Company’s ordinary shares were voluntarily delisted from the Tel Aviv Stock Exchange (“TASE”). The ordinary shares of the Company continue to be listed on the Nasdaq Capital Market in the form of ADSs.

- b. Going Concern

The accompanying financial statements have been prepared in conformity with International Financial Reporting Standards (IFRS), assuming that the Company will continue to operate as a going concern. During the year ended December 31, 2018, the Company incurred a net loss of NIS 20,113 (\$5,367) and had negative cash flows from operating activities of NIS 23,635 (\$6,306). In addition, the Company had an accumulated deficit of NIS 84,056 (\$22,427) at December 31, 2018. The Company’s management plans to seek additional equity financing. The Company believes its current capital resources are sufficient to support its operations through the end of the first quarter of 2020.

The Company’s activities since inception have consisted of raising capital and performing research and development activities. As of December 31, 2018, principal commercial operations have not commenced. Successful completion of the Company’s development programs and, ultimately, the attainment of profitable operations, if any, are dependent on future events, including, among other things, its ability to obtain marketing approval from regulatory authorities and access potential markets, secure financing, develop a customer base, attract, retain and motivate qualified personnel and develop strategic alliances. Although management believes that the Company will be able to successfully fund its operations, see note 14 for fundraised at February 2019, there can be no assurance that the Company will be able to do so or that the Company will ever operate profitably.

The Company expects to continue to incur substantial losses over the next several years during its development phase. To fully execute its business plan, the Company will need, among other things, to complete its research and development efforts and clinical and regulatory activities. These activities may take several years and will require significant operating and capital expenditures in the foreseeable future. There can be no assurance that these activities will be successful. If the Company is not successful in these activities it could delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities. To fund its capital needs, the Company plans to raise funds through equity or debt financings or other sources, such as strategic partnerships and alliance and licensing arrangements, and in the long term, from the proceeds from sales.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data**

NOTE 1:- GENERAL (Cont.)

Additional funds may not be available when the Company needs them, on terms that are acceptable to it, or at all. These matters raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if the Company was unable to continue as a going concern.

- c. The Company currently relies on a single source supplier for one of the components used for R&D. If the current supplier suffers a major natural or man-made disaster at its manufacturing facility, or if it were otherwise cease to supply to us, then this could result in further delays in the clinical studies and may delay product testing and potential regulatory approval until a qualified alternative supplier is identified.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The following accounting policies have been applied consistently in the consolidated financial statements for all periods presented, unless otherwise stated.

- a. Basis of presentation of the financial statements:

These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS"). The Company's financial statements have been prepared on a cost basis, except for marketable securities and liability related to warrants that are measured at fair value through profit or loss. The Company has elected to present profit or loss items using the "function of expense" method. The Company's operating cycle is one year.

- b. Consolidated financial statements:

The consolidated financial statements include the financial statements of companies that are controlled by the Company (subsidiaries). Control is achieved when the Company is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. Potential voting rights are considered when assessing whether an entity has control. The consolidation of the financial statements commences on the date on which control is obtained and ends when such control ceases.

The financial statements of the Company and its subsidiaries (the "Group") are prepared as of the same dates and periods. The consolidated financial statements are prepared using uniform accounting policies by all companies in the Group. Significant intercompany balances and transactions and gains or losses resulting from intragroup transactions are eliminated in full in the consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data**

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

c. Functional currency, reporting currency and foreign currency:

1. Functional currency and reporting currency:

The presentation currency and the group currency of the financial statements is the New Israeli Shekel ("NIS").

The Company determines the functional currency of each company in the Group. The functional currency used to measure the financial condition and results of operations of each company separately.

2. Transactions, assets and liabilities in foreign currency:

Transactions denominated in foreign currency are recorded upon initial recognition at the exchange rate at the date of the transaction. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated on each reporting date into the functional currency at the exchange rate at that date. Exchange rate differences are recognized in profit or loss.

d. Convenience translation into U.S. dollars:

The financial statements as of December 31, 2018 and for the year then ended have been translated into U.S. dollars using the exchange rate of the U.S. dollar as of December 31, 2018 (U.S. \$1.00 = NIS 3.748). The translation was made solely for convenience purposes.

The dollar amounts presented in these financial statements should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated.

e. Cash equivalents:

Cash equivalents are considered as highly liquid investments, including unrestricted short-term bank deposits with an original maturity of three months or less from the date of investment or with a maturity of more than three months, but which are redeemable on demand without penalty and which form part of the Group's cash management.

f. Restricted cash:

Restricted cash is primarily invested to secure credit card payments and is used as security for the Company's lease commitment.

g. Taxes on income:

Current or deferred taxes are recognized in profit or loss, except to the extent that they relate to items which are recognized in other comprehensive income or equity.

1. Current taxes

The current tax liability is measured using the tax rates and tax laws that have been enacted or substantively enacted by the reporting date as well as adjustments required in connection with the tax liability in respect of previous years.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

2. Deferred taxes

Deferred taxes are measured at the tax rate that is expected to apply when the asset is realized or the liability is settled, based on tax laws that have been enacted or substantively enacted by the reporting date.

Deferred tax assets are reviewed at each reporting date and reduced to the extent that it is not probable that they will be utilized. Deductible carryforward losses and temporary differences for which deferred tax assets had not been recognized are reviewed at each reporting date and a respective deferred tax asset is recognized to the extent that their utilization is probable.

Taxes that would apply in the event of the disposal of investments in investees have not been taken into account in computing deferred taxes, as long as the disposal of the investments in investees is not probable in the foreseeable future. Also, deferred taxes that would apply in the event of distribution of earnings by investees as dividends have not been taken into account in computing deferred taxes, since the distribution of dividends does not involve an additional tax liability or since it is the Company's policy not to initiate distribution of dividends from a subsidiary that would trigger an additional tax liability.

Taxes on income that relate to distributions of an equity instrument and to transaction costs of an equity transaction are accounted for pursuant to IAS 12.

Deferred taxes are offset if there is a legally enforceable right to offset a current tax asset against a current tax liability and the deferred taxes relate to the same taxpayer and the same taxation authority.

h. Property, plant and equipment:

Property, plant and equipment are measured at cost, including directly attributable costs, less accumulated depreciation.

Depreciation is calculated on a straight-line basis over the useful life of the assets at annual rates as follows:

	%
Computers and Electronic Equipment	33
Laboratory and clinical experiments equipment	15
Leasehold improvements	(*)
Office furniture and equipment	7 - 15

(*) Leasehold improvements are depreciated on a straight-line basis over the earlier of the lease term or the estimated useful life of the improvement.

The useful life, depreciation method and residual value of an asset are reviewed at least each year-end and any changes are accounted for prospectively as a change in accounting estimate.

Depreciation of an asset ceases at the earlier of the date that the asset is classified as held for sale and the date that the asset is derecognized.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data**

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

i. Research and development expenses, net of participations:

Research and development expenses are recognized in profit or loss when incurred. An intangible asset arising from a development project or from the development phase of an internal project is recognized if the Company can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale; the Company's intention to complete the intangible asset and use or sell it; the Company's ability to use or sell the intangible asset; how the intangible asset will generate future economic benefits;

The availability of adequate technical, financial and other resources to complete the intangible asset; and the Company's ability to measure reliably the expenditure attributable to the intangible asset during its development.

j. Government grants:

Government grants are recognized when there is reasonable assurance that the grants will be received and the Company will comply with the attached conditions. Government grants received from the Israel-U.S. Binational Industrial Research and Development ("BIRD") Foundation are recognized upon receipt as a reduction in research and development expenses, as the Company evaluated that there is reasonable assurance that the Company will not be required to pay royalties, based on the best estimate of future sales using the original effective method.

k. Impairment of non-financial assets:

The Company evaluates the need to record an impairment of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable.

If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount. The recoverable amount is the higher of fair value less costs of sale and value in use. In measuring value in use, the expected future cash flows are discounted using a pre-tax discount rate that reflects the risks specific to the asset. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs. Impairment losses are recognized in profit or loss.

An impairment loss of an asset, other than goodwill, is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, shall not be increased above the lower of the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years and its recoverable amount. The reversal of impairment loss of an asset presented at cost is recognized in profit or loss.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data**

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

1. Financial assets:

Financial assets are measured upon initial recognition at fair value plus transaction costs that are directly attributable to the acquisition of the financial assets, except for financial assets measured at fair value through profit or loss in respect of which transaction costs are recorded in profit or loss.

The Company classifies and measures debt instruments in the financial statements based on the following criteria:

- The Company's business model for managing financial assets; and
- The contractual cash flow terms of the financial asset.

a) Debt instruments are measured at amortized cost when:

The Company's business model is to hold the financial assets in order to collect their contractual cash flows, and the contractual terms of the financial assets give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding. After initial recognition, the instruments in this category are measured according to their terms at amortized cost using the effective interest rate method, less any provision for impairment.

On the date of initial recognition, the Company may irrevocably designate a debt instrument as measured at fair value through profit or loss if doing so eliminates or significantly reduces a measurement or recognition inconsistency, such as when a related financial liability is also measured at fair value through profit or loss.

b) Debt instruments are measured at fair value through other comprehensive income when:

The Company's business model is to hold the financial assets in order to both collect their contractual cash flows and to sell the financial assets, and the contractual terms of the financial assets give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

After initial recognition, the instruments in this category are measured at fair value. Gains or losses from fair value adjustments, excluding interest and exchange rate differences, are recognized in other comprehensive income.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

- c) Debt instruments are measured at fair value through profit or loss when:

A financial asset which is a debt instrument does not meet the criteria for measurement at amortized cost or at fair value through other comprehensive income. After initial recognition, the financial asset is measured at fair value and gains or losses from fair value adjustments are recognized in profit or loss.

- d) Equity instruments and other financial assets held for trading:

Investments in equity instruments do not meet the above criteria and accordingly are measured at fair value through profit or loss.

Other financial assets held for trading such as derivatives, including embedded derivatives separated from the host contract, are measured at fair value through profit or loss unless they are designated as effective hedging instruments.

In respect of certain equity instruments that are not held for trading, on the date of initial recognition, the Company made an irrevocable election to present subsequent changes in fair value in other comprehensive income which changes would have otherwise been recorded in profit or loss. These changes will not be reclassified to profit or loss in the future, even when the investment is disposed of.

Dividends from investments in equity instruments are recognized in profit or loss when the right to receive the dividends is established.

Financial liabilities:

Financial liabilities measured at amortized cost:

Financial liabilities are initially recognized at fair value less transaction costs that are directly attributable to the issue of the financial liability.

After initial recognition, the Company measures all financial liabilities at amortized cost using the effective interest rate method, except for:

- Financial liabilities at fair value through profit or loss such as derivatives;
- Financial liabilities that arise when a transfer of a financial asset does not qualify for derecognition or when the continuing involvement approach applies;
- Financial guarantee contracts;
- Commitments to provide a loan at a below-market interest rate;
- Contingent consideration recognized by an acquirer in a business combination to which IFRS 3 applies.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

m. Fair value measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

Fair value measurement is based on the assumption that the transaction will take place in the asset's or the liability's principal market, or in the absence of a principal market, in the most advantageous market.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

Fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

All assets and liabilities measured at fair value or for which fair value is disclosed are categorized into levels within the fair value hierarchy based on the lowest level input that is significant to the entire fair value measurement:

Level 1 - quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 - inputs other than quoted prices included within Level 1 that are observable directly or indirectly.

Level 3 - inputs that are not based on observable market data (valuation techniques which use inputs that are not based on observable market data).

The following table presents the fair value measurement hierarchy for the Group's liabilities.

Quantitative disclosures of the fair value measurement hierarchy of the Group's liabilities as of December 31, 2018 and December 31, 2017:

	December 31, 2018		
	Fair value measurements using input type		
	Level 1	Level 2	Total
Financial liabilities related to Warrants to ADS	(1,816)	-	(1,816)
ADSs for consultants	(203)	-	(203)
Share based compensation	-	(3,421)	(3,421)
Total financial net assets (liabilities)	(2,019)	(3,421)	(5,440)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

	December 31, 2017		
	Fair value measurements using input type		
	Level 1	Level 2	Total
Marketable securities	13,999	-	13,999
Financial liabilities related to Warrants to ADS	(7,090)	(332)	(7,422)
ADSs for consultants	(643)	-	(643)
Share based compensation	-	(8,267)	(8,267)
Total financial net assets (liabilities)	6,266	(8,599)	(2,333)

n. Treasury shares

The Company's shares held by the Company are measured at their acquisition cost and are presented as an offset against the Company's equity. Any gain or loss deriving from the purchase, sale, issuance or cancellation of treasury shares is recognized directly in equity.

o. Employee benefit liabilities:

The Group has several employee benefit plans:

1. Short-term employment benefits:

Short-term employee benefits are benefits that are expected to be settled wholly before twelve months after the end of the annual reporting period in which the employees render the related services. These benefits include salaries, paid annual leave, paid sick leave, recreation and social security contributions and are recognized as expenses as the services are rendered. A liability in respect of a cash bonus or a profit-sharing plan is recognized when the Group has a legal or constructive obligation to make such payment as a result of past service rendered by an employee and a reliable estimate of the amount can be made.

2. Post-employment benefits:

Post-employment benefit plans are normally funded by contributions to insurance companies and are classified as defined contribution plans.

The Company has defined contribution plans pursuant to Section 14 of the Israeli Severance Pay Law, into which the Company pays fixed contributions and has no legal or constructive obligation to pay further contributions on account of severance pay, even if the fund does not hold sufficient amounts to pay all employee benefits relating to employee service in current and prior periods.

Contributions to the defined contribution plan in respect of severance or retirement pay are recognized as an expense when contributed concurrently with performance of the employee's services.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data**

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

p. Share-based payment transactions:

The Company's employees/other service providers are entitled to remuneration in the form of equity-settled share-based payment transactions and certain employees/other service providers are entitled to remuneration in the form of cash-settled share-based payment transactions that are measured based on the increase in the Company's share price.

Equity-settled transactions:

The cost of equity-settled transactions with employees is measured at the fair value of the equity instruments granted at grant date. The fair value is determined using an acceptable option pricing model.

As for other service providers, the cost of the transactions is measured at the fair value of the goods or services received as consideration for equity instruments granted.

In case where the fair value of the goods or services received as consideration of equity instruments cannot be measured, they are measured by reference to the fair value of the equity instruments granted.

The cost of equity-settled transactions is recognized in profit or loss, together with a corresponding increase in equity, during the period in which the performance or service conditions are satisfied, and ending on the date on which the relevant employees become fully entitled to the award (the "Vesting Period").

No expense is recognized for awards that do not ultimately vest, except for awards where vesting is conditional upon a market condition, which are treated as vested irrespective of whether the market condition is satisfied, provided that all other vesting conditions (service and/or performance) are satisfied.

If the Company modifies the conditions on which equity-instruments were granted, an additional expense is recognized for any modification that increases the total fair value of the share-based payment arrangement or is otherwise beneficial to the employee/other service provider at the modification date.

If a grant of an equity instrument is cancelled, it is accounted for as if it had vested on the cancellation date and any expense not yet recognized for the grant is recognized immediately. However, if a new grant replaces the cancelled grant and is identified as a replacement grant on the grant date, the cancelled and new grants are accounted for as a modification of the original grant, as described above.

q. Loss per share:

Loss per share is calculated by dividing the net loss attributable to Company shareholders by the weighted number of outstanding ordinary shares during the period. Potential ordinary shares are only included in the computation of diluted loss per share when their conversion increases loss per share or decreases income per share. Potential ordinary shares that are converted during the period are included in diluted loss per share only until the conversion date and from that date in basic loss per share.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data**

NOTE 3:- SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN PREPARATION OF THE FINANCIAL STATEMENTS*Estimates and assumptions:*

The preparation of the Group's financial statements requires management to make estimates and assumptions that have an effect on application of the accounting policies and on the reported amounts of assets, liabilities and expenses. Changes in accounting estimates are reported in the period of the change in estimate.

The key assumptions made in the financial statements concerning uncertainties at the reporting date and the critical estimates computed by the Company that may result in a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

- Determining the fair value of share-based transactions

The fair value of share based transactions is determined upon initial recognition using acceptable option pricing models. The model is based on per-share price data and the exercise price and assumptions regarding expected volatility, expected life, expected dividend and risk-free interest rate.

NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION

IFRS 16, "Leases":

In January 2016, the IASB issued IFRS 16, "Leases" ("the new Standard"). According to the new Standard, a lease is a contract, or part of a contract, that conveys the right to use an asset for a period of time in exchange for consideration.

The effects of the adoption of the new Standard are as follows:

- According to the new Standard, lessees are required to recognize all leases in the statement of financial position (excluding certain exceptions, see below). Lessees will recognize a liability for lease payments with a corresponding right-of-use asset, similar to the accounting treatment for finance leases under the existing standard, IAS 17, "Leases". Lessees will also recognize interest expense and depreciation expense separately.
- Variable lease payments that are not dependent on changes in the Consumer Price Index ("CPI") or interest rates, but are based on performance or use are recognized as an expense by the lessees as incurred and recognized as income by the lessors as earned.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data****NOTE 4:- DISCLOSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (Cont.)**

- In the event of change in variable lease payments that are CPI-linked, lessees are required to remeasure the lease liability and record the effect of the remeasurement as an adjustment to the carrying amount of the right-of-use asset.
- The accounting treatment by lessors remains substantially unchanged from the existing standard, namely classification of a lease as a finance lease or an operating lease.
- NOTE 4:- The new Standard includes two exceptions which allow lessees to account for leases based on the existing accounting treatment for operating leases - leases for which the underlying asset is of low financial value and short-term leases (up to one year).

The new Standard is effective for annual periods beginning on or after January 1, 2019.

The new Standard permits lessees to use one of the following approaches:

1. Full retrospective approach - according to this approach, a right-of-use asset and the corresponding liability will be presented in the statement of financial position as if they had always been measured according to the provisions of the new Standard. Accordingly, the effect of the adoption of the new Standard at the beginning of the earliest period presented will be recorded in equity. Also, the Company will restate the comparative data in its financial statements. Under this approach, the balance of the liability as of the date of initial application of the new Standard will be calculated using the interest rate implicit in the lease, unless this rate cannot be easily determined in which case the lessee's incremental borrowing rate of interest on the commencement date of the lease will be used.
2. Modified retrospective approach - this approach does not require restatement of comparative data. The balance of the liability as of the date of initial application of the new Standard will be calculated using the lessee's incremental borrowing rate of interest on the date of initial application of the new Standard. As for the measurement of the right-of-use asset, the Company may choose, on a lease-by-lease basis, to apply one of the two following alternatives:
 - Recognize an asset in an amount equal to the lease liability, with certain adjustments.
 - Recognize an asset as if the new Standard had always been applied.

The Company believes that it will apply the modified retrospective approach upon the initial adoption of the new Standard by measuring the right-of-use asset at an amount equal to the lease liability, as measured on the transition date.

The Company believes, based on an assessment of the impact of the adoption of the new Standard, that its application is not expected to have a material effect on the financial statements. The first assumption of the company is that the asset and liability will be in the amount of NIS 868 at the date of recognition.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 5:- MARKETABLE SECURITIES MEASURED AT FAIR VALUE THROUGH PROFIT AND LOSS

Marketable securities are measured at fair value through profit and loss. During 2018 and as of December 31 2017, the marketable securities are comprised of NIS mutual funds that follow changes in short term Bank of Israel interest.

NOTE 6:- OTHER RECEIVABLES

	December 31,		Convenience translation (Note 2d)
	2017	2018	December 31,
	N I S		2018
			U.S. dollars
Other receivables	60	30	8
Government authorities	185	186	50
Prepaid expenses	573	600	160
	<u>818</u>	<u>816</u>	<u>218</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 7:- PROPERTY, PLANT AND EQUIPMENT, NET

Balance as of December 31, 2018:

	<u>Laboratory equipment</u>	<u>Leasehold improvements</u>	<u>Office furniture and equipment</u>	<u>Computers</u>	<u>Total</u>
Cost					
Balance as of January 1, 2018	1,250	384	171	295	2,100
Additions during the year	<u>527</u>	<u>12</u>	<u>49</u>	<u>64</u>	<u>652</u>
Balance as of December 31, 2018	<u>1,777</u>	<u>396</u>	<u>220</u>	<u>359</u>	<u>2,752</u>
Accumulated Depreciation					
Balance as of January 1, 2018	302	241	31	182	756
Additions during the year:	<u>234</u>	<u>125</u>	<u>14</u>	<u>79</u>	<u>452</u>
Balance as of December 31, 2018	<u>536</u>	<u>366</u>	<u>45</u>	<u>261</u>	<u>1,208</u>
Depreciated cost as of December 31, 2018	<u>1,241</u>	<u>30</u>	<u>175</u>	<u>98</u>	<u>1,544</u>
Depreciated cost as of December 31, 2018 (convenience translation into U.S. dollars (Note 2d))	<u>331</u>	<u>8</u>	<u>46</u>	<u>27</u>	<u>412</u>

Balance as of December 31, 2017:

	<u>Laboratory equipment</u>	<u>Leasehold improvements</u>	<u>Office furniture and equipment</u>	<u>Computers</u>	<u>Total</u>
Cost					
Balance as of January 1, 2017	1,006	372	147	232	1,757
Additions during the year	244	12	24	65	345
Deductions during the year	<u>-</u>	<u>-</u>	<u>-</u>	<u>(2)</u>	<u>(2)</u>
Balance as of December 31, 2017	<u>1,250</u>	<u>384</u>	<u>171</u>	<u>295</u>	<u>2,100</u>
Accumulated Depreciation					
Balance as of January 1, 2017	140	116	18	110	384
Additions during the year:	<u>162</u>	<u>125</u>	<u>13</u>	<u>72</u>	<u>372</u>
Balance as of December 31, 2017	<u>302</u>	<u>241</u>	<u>31</u>	<u>182</u>	<u>756</u>
Depreciated cost as of December 31, 2017	<u>948</u>	<u>143</u>	<u>140</u>	<u>113</u>	<u>1,344</u>
Depreciated cost as of December 31, 2017 (convenience translation into U.S. dollars (Note 2d))	<u>274</u>	<u>41</u>	<u>40</u>	<u>33</u>	<u>388</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 8:- OTHER PAYABLES

	December 31,		Convenience translation (Note 2d)
	2017	2018	December 31,
	N I S		2018
			U.S. dollars
Employees and payroll accruals *)	1,954	2,317	618
Accrued expenses	430	1,499	400
Other	12	196	52
	<u>2,396</u>	<u>4,012</u>	<u>1,070</u>

*) Balance includes related parties (The Company's CEO and the Chairman of the Board of Directors).

NOTE 9:- EQUITY

a. Changes in share capital:

	Number of Shares (issued and outstanding)
<u>Balance as of January 1, 2017</u>	*) 107,628,485
Issuance of shares and warrants	10,622,720
Exercise of share options	1,484,154
ADS granted (see Note 12c)	450,300
<u>Balance as of December 31, 2017</u>	*) 120,185,659
Issuance of shares and warrants	9,696,960
Exercise of share options	310,180
ADS granted (see Note 12c)	222,000
<u>Balance as of December 31, 2018</u>	*) 130,414,799

*) Net of 2,641,693 treasury shares of the Company, held by the Company.

- In February 2016, the Company completed a private placement of shares and warrants for a total of approximately NIS 8,000 and issued 5,783,437 ordinary shares as well as 1,927,801 unlisted warrants exercisable for a period of 12 months, at an exercise price of NIS 2.1 per warrant. Participants in the private placement also included related parties and an officer of the Company. On May 16, 2016, the Company's shareholders, at a general meeting, approved the participation of the controlling shareholder and Chairman of the Board, Nuriel Kasbian Chirich, in the private placement, and accordingly he was allotted 287,769 shares and 95,923 unlisted warrants of the Company on the same terms as the rest of the offerees. On January 9, 2017, the Company's shareholders, at general meeting of the Company's shareholders, approved the extension of the exercise period of the warrants until March 7, 2018. At March 7, 2018 the unlisted warrants expired.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data**

NOTE 9:- EQUITY (Cont.)

- On July 28, 2016, the Company completed a US initial public offering (the "IPO") of 1,292,308 ADSs and listed warrants to purchase 969,231 ADSs (the "Listed Warrants") at a combined price to the public of \$6.50 resulting in gross proceeds of NIS 32,107, (NIS 25,820 net of all issuance costs, including share-based awards granted). An amount of NIS 23,269 out of the consideration was related to the ADSs and classified as equity component, while an amount of NIS 3,173 was related to the fair value of the Listed Warrants and was classified as a liability. Issuance costs amounting to NIS 622 associated with the issuance of the Listed Warrants and have been recognized as finance expenses.

Each Listed Warrant is exercisable into one ADS, for a period of five years at an exercise price of US\$7.50 per warrant. Since the warrant exercise price is in US dollars, which is not the Company's functional currency, the Listed Warrants were classified as a financial liability at fair value and are marked to market through profit or loss in accordance with IFRS 9.

The Company granted the underwriters a 45-day over-allotment option to purchase up to 193,846 additional ADSs at a price of US\$6.038 per ADS and/or additional Listed Warrants to purchase 145,385 ADSs, on the same terms as the warrants issued to the public, at a price of US\$0.007 per warrant. The underwriters partially exercised the over-allotment option resulting in the issuance of 65,890 Listed Warrants. The option to the Underwriters was recognized as a share based payment transaction in accordance with IFRS 2, and was netted off the total consideration as issuance cost.

Furthermore, the Company issued to the underwriters unlisted warrants to purchase 77,538 ADSs at an exercise price of \$8.80 per warrant and exercisable for a period of four years. The underwriters' unlisted warrants were classified as a share based payment transaction in accordance with IFRS 2 and netted off the total consideration as issuance cost. On April 4, 2017, underwriters' warrants to purchase 61,487 ADSs were exercised.

- On May 9, 2017, the Company's shareholders at a general shareholders' meeting approved the following changes in the terms of the options (Series 1): (i) extension of the expiration date options (Series 1) to a date that is 80 days from court approval for such of the exercise period of the options (Series 1) (i.e. August 17, 2017, following court approval), and (ii) reduction in the exercise price of the options (Series 1) from NIS 1.85 per option to NIS 1.20 per option, in accordance with Section 350 of the Israeli Companies Law. On May 29, 2017, the court approved the changes to the options (Series 1). On August 17, 2017 the options (Series 1) expired.
- Between July 1, 2017, and August 16, 2017, an aggregate of 516,574 options (Series 1) were exercised. Each option (Series 1) was exercised into one ordinary share at an exercise price of NIS 1.20 per option.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data****NOTE 9:- EQUITY (Cont.)**

5. On September 7, 2017, the Company sold to certain accredited investors an aggregate of 531,136 ADSs and 265,568 unregistered warrants to purchase 265,568 ADSs in a registered direct offering at \$8.10 per ADS in which it raised gross proceeds of NIS 15,214, (NIS 13,970 net of all issuance costs, including share-based awards granted). An amount of NIS 11,695 out of the consideration related to the ADSs and classified as equity component, while an amount of NIS 2,481 related to the fair value of the warrants, calculate by the Black-Scholes model, to purchase ADSs and was classified as a liability. Issuance costs amounting to NIS 204 associated with the issuance of the warrants, have been recognized as finance expenses. The investor warrants were exercisable for one year from issuance and had an exercise price of \$12.07 per ADS, subject to adjustment as set forth therein. The investor warrants were exercisable on a cashless basis if there were no effective registration statement registering the ADSs underlying the warrants. The Company paid approximately \$140 in placement agent fees and expenses and issued unregistered placement agent warrants to purchase 7,492 ADSs on the same general terms as the investor warrants except they have an exercise price of \$10.125 per ADS. On September 10, 2018 all the investor warrants and the placement agent warrants were expired.

Since the warrant exercise price is in US dollars, which is not the Company's functional currency, the unregistered warrants to purchase ADS were classified as a financial liability at fair value and are marked to market through profit or loss.

The placement agent warrants were classified as a share based payment transaction in accordance with IFRS 2 and netted off the total consideration as issuance cost.

6. On January 31, 2018, the Company sold to certain institutional investors an aggregate of 484,848 ADSs and 266,667 unregistered warrants to purchase 266,667 ADSs in a registered direct offering at \$8.25 per ADS in which it raised gross proceeds of NIS 13,620 (NIS 11,865 net of all issuance costs in the amount of NIS 1,755, including share-based awards granted). An amount of NIS 10,024 out of the consideration related to the ADSs and classified as equity component, while an amount of NIS 2,113 related to the fair value of the warrants, calculate by the Black-Scholes model, to purchase ADSs and was classified as a liability. Issuance costs amounting to NIS 272 associated with the issuance of the warrants, have been recognized as finance expenses. The investor warrants may be exercised for one year from issuance and have an exercise price of \$12.00 per ADS, subject to adjustment as set forth therein. The investor warrants may be exercised on a cashless basis if there is no effective registration statement registering the ADSs underlying the warrants. As part of the issuance costs, the Company paid approximately \$323 in placement agent fees and expenses and issued unregistered placement agent warrants to purchase 24,242 ADSs on the same general terms as the investor warrants except they have an exercise price of \$10.31 per ADS.

Since the warrant exercise price is in US dollars, which is not the Company's functional currency, the unregistered warrants to purchase ADS were classified as a financial liability at fair value and are marked to market through profit or loss in accordance with IFRS 9.

The placement agent warrants were classified as a share based payment transaction in accordance with IFRS 2, and was netted off the total consideration as issuance cost.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data**

NOTE 9:- EQUITY (Cont.)

b. Rights related to ordinary shares

All ordinary shares shall have equal rights and each ordinary share shall entitle the holder the following rights:

1. The right to receive notices of any general meeting of shareholders, to participate in meetings and vote on any matter raised in the meeting. Each ordinary share entitles its holder to one vote.
2. The right to participate in any distribution by the Company to its shareholders and receive dividends and / or bonus shares, if distributed in accordance with the Company articles of association.
3. The right to participate at the time of liquidation of the Company, in the distribution of the Company's assets permitted to be distributed in proportion to the number of shares allocated and the degree of repayment by the shareholders, if not fully paid, and subject to the provisions of the articles of association of the Company and without prejudice to existing rights of shareholders of any kind.

NOTE 10:- SHARE-BASED COMPENSATION

- a. In February 2014, the Company's board of directors adopted an Employee Shares Incentive Plan (the "2014 Plan"). Under the 2014 Plan, options may be granted to employees, officers, directors, consultants, advisers and service providers of the Company.

On May 17, 2018, the board of directors approved an increase to the Company's option pool of 4,392,029 options. As a result, the Company has a total of 17,100,000 options in the pool.

- b. On November 23, 2015, the Company's shareholders, at a general meeting of shareholders approved the former Deputy CEO and CFO terms of service, including a grant of options, which is an exception from the Company's compensation policy, as further described below. The terms of service included among others, a grant of 2,658,246 options, exercisable for 2,658,246 ordinary shares, no par value, of the Company at an exercise price of NIS 1.286 per share. The total benefit in respect of the grant calculated at the grant date was NIS 3,033.

On March 28, 2017, 500,000 options were exercised into 500,000 ordinary shares by the Company's former Deputy CEO and CFO.

During January, 2018, 310,180 options were exercised into 310,180 ordinary shares by the Company's former Deputy CEO and CFO. The remaining 297,420 options expired on February 28, 2018.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 10:- SHARE-BASED COMPENSATION (Cont.)

c. Details on share-based payment for service providers:

1. On February 28, 2017, the board of directors approved the issuance to a consultant of 15,000 ADSs. The issuance was made in three equal tranches, of 5,000 ADSs each. The first tranche was issued in May 2017, the second tranche was issued in July 2017 and the third tranche was issued in November 2017.
2. On July 23, 2017, the Company issued 7,515 ADSs to a consultant. On June 28, 2017, the board of directors approved the issuance of ADSs.
3. On November 26, 2018 the Company issued 9,000 ADSs to a consultant. On November 12, 2018, the board of directors approved the issuance of ADSs.
4. On December 2, 2018 the Company issued 2,100 ADSs to a consultant. On November 12, 2018, the board of directors approved the issuance of ADSs. In addition the Company issued warrants to purchase 4,500 ADSs exercisable at \$4.803 per ADS for one year from the agreement date and are fully vested from the issuance date.

d. Expense recognized in the financial statements:

The expense that was recognized for services received from employees, directors and service providers is as follows:

	Year ended December 31,			Convenience translation (Note 2d)
	2016	2017	2018	Year ended December 31, 2018 U.S. dollars
	N I S			
Research and development	253	1,940	807	215
General and administrative	1,299	3,444	3,730	996
Total share-based compensation	1,552	5,384	4,537	1,211

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 10:- SHARE-BASED COMPENSATION (Cont.)

e. Activity during the year:

The table below includes the number of share options, and the weighted average of their exercise prices:

	2017		2018	
	Number of options	Weighted Average Exercise price NIS	Number of options	Weighted Average Exercise price NIS
Outstanding at beginning of year	5,979,973	1.25	10,752,668	1.18
Options exercised for shares	(696,980)	1.16	(310,180)	1.29
Options forfeited	(166,667)	0.63	(170,375)	1.34
Option Expired	(726,512)	1.69	(693,756)	1.39
Granted	6,362,854	1.16	3,435,790	1.21
Outstanding at end of year	10,752,668	1.18	13,014,147	1.18

f. The following table summarize information about the Company's outstanding and exercisable options granted to employees and consultants as of December 31, 2018:

Exercise price (Range)	Options outstanding as of December 31, 2018	Weighted average remaining contractual term (years)	Options exercisable as of December 31, 2018	Weighted average remaining contractual term (years)
0.001 - 1.35	10,129,937	8.4	3,802,949	8.0
1.35 - 1.8	2,596,210	7.4	1,445,688	6.0
1.8 - 2.1	288,000	6.6	288,000	6.6
	13,014,147	8.2	5,536,637	7.4

g. Measuring the fair value of share options settled by equity instruments:

The Company measures the fair value of the options under the Black-Scholes model. Fair values were estimated using the following assumptions for the years ended December 31, 2017 and 2018, is as follows:

	2017	2018
Dividend yield (%)	0	0
Expected volatility of the share prices (%)	81.56%-85.61%	59.23%-84.66%
Risk-free interest rate (%)	1.94%-2.52%	1.86%-3.19%
Expected life of share options (years)	10	1-10

Based on the assumptions above, the fair value of options granted in the years 2017-2018 was NIS 11,688 at the grant date.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data**

NOTE 10:- SHARE-BASED COMPENSATION (Cont.)

The determination of the grant date fair value of options using an option pricing model (the Company utilizes the Black-Scholes model) is affected by estimates and assumptions regarding a number of complex and subjective variables. These variables include the expected volatility of the Company's share price over the expected term of the options, share option exercise and cancellation behaviors, risk-free interest rates and expected dividends, which are estimated as follows:

1. The expected share price volatility is based on the historical volatility in the trading price of the Company's ordinary shares as well as comparable companies on the TASE and on the Nasdaq and benchmarks of related companies.
2. The expected term of options granted is based upon the contractual life of the options and represents the period of time that options granted are expected to be outstanding.
5. The risk-free interest rate is based on the yield from Israeli government bonds with a term equivalent to the contractual life of the options.
6. The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero.

NOTE 11:- TAXES ON INCOME**a. Corporate tax rates in Israel:**

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2017 which reduces the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018.

The Israeli corporate income tax rate was 23% in 2018, 24% in 2017 and 25% in 2016.

A company incorporated in the U.S. - weighted tax rate of about 21% (Federal tax, State tax and city tax of the city where the company operates).

Collect Biotech Inc is subject to the U.S. federal tax reform (Tax Cuts and Jobs Act of 2017).

b. Final tax assessments:

The Company and its subsidiary received final tax assessments through tax years 2012.

In 2018, the Company received final tax assessments for the years 2013-2016 following an audit of the income tax of ITA.

c. Net operating carry forwards losses for tax purposes and other temporary differences:

As of December 31, 2018, the Company had carry forward operating losses amounting to approximately NIS 70,057.

The Company did not recognize deferred tax assets for carry forward operating and capital losses and other temporary differences because their utilization in the foreseeable future is not probable.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**In thousands, except number of shares data**

NOTE 12:- CONTINGENT LIABILITIES AND COMMITMENTS

a. Commitments

1. On September 1, 2015, the Company signed a lease agreement for new offices. The aforementioned lease agreement is for a minimum period of three years from the date of signing the agreement. On October 15, 2018 the lease agreement was extended for two additional years until October 14, 2020. During 2018, the Company signed a new lease agreement for additional offices in the same building. The aforementioned lease agreement, is for a minimum period of 18 months.

The future minimum lease fees payable as of December 31, 2018 are NIS 570, NIS 414, for the years 2019, 2020 respectively.

The Company has entered into operating lease agreements for vehicles. These leases have an average life of three years with no option to extend the contract. The Company has the right to terminate the agreement before the end of the three years and will be required to pay an early termination penalty of between one to three months of the lease.

The future minimum lease fees payable as of December 31, 2018 are NIS 159, NIS 139, NIS 56, for the years 2019, 2020, 2021 respectively.

2. The Company participated in programs sponsored by the Israel-United States Binational Industrial Research and Development Foundation (BIRD) for the support of research and development activities. The Company is obligated to pay royalties to BIRD, amounting to 5% of the gross sales of the products and other related revenues developed from such activities, up to an amount of 150% from the grant received from BIRD by the Company indexed to the U.S. consumer price index.

As of December 31, 2018, the Company received an aggregate grant of \$120 from the BIRD Foundation in support of the development and commercialization of the Company's stem cell selection technology in collaboration with Entegris. The Company is no longer pursuing its collaboration with Entegris and does not expect to receive additional grants in the future.

b. Liens:

The Company provided a NIS 175 restricted bank deposit to secure credit card payments.

The Company provided a NIS 162 restricted bank deposit to secure the rent payment.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 13:- BALANCES AND TRANSACTIONS WITH RELATED PARTIES

- a. Related party balances

	December 31				Convenience translation (Note 2d) Year ended December 31, 2018	
	2017		2018		Key management personnel	Other related parties
	Key management personnel	Other related parties	Key management personnel	Other related parties		
	NIS				U.S. Dollars	
Other payables	425	827	687	848	183	226
	425	827	687	848	183	226

- b. The directors and senior managers of the Company are entitled, in addition to salary, to non-cash benefits (such as a car, medical insurance, etc.).

Benefits for employment of key management personnel (including directors) employed in the Company:

	Year ended December 31,						Convenience translation (Note 2d) Year ended December 31, 2018
	2016		2017		2018		2018
	No. of people	Amount NIS	No. of people	Amount NIS	No. of people	Amount NIS	Amount U.S. dollars
Short-term employee benefits (includes Company's CEO in 2016, 2017 and 2018)	7	6,040	5	7,816	8	8,790	2,345

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 13:- BALANCES AND TRANSACTIONS WITH RELATED PARTIES (Cont.)

- c. Benefits for employment of key management personnel (including directors) that are not employed in the Company:

	Year ended December 31,						Convenience translation (Note 2d)
	2016		2017		2018		Year ended December 31, 2018
	No. of people	Amount NIS	No. of people	Amount NIS	No. of people	Amount NIS	Amount U.S. dollars
Key management personnel and related parties	-	-	-	-	-	-	-
Directors' fees	5	513	8	682	7	1,027	274
	<u>5</u>	<u>513</u>	<u>8</u>	<u>682</u>	<u>7</u>	<u>1,027</u>	<u>274</u>

- d. Transactions with related parties:

	Year ended December 31,						Convenience translation (Note 2d)	
	2016		2017		2018		Year ended December 31, 2018	
	Key management personnel	Related parties	Key management personnel	Related parties	Key management personnel	Related parties	Key management personnel	Related parties
Research and development expenses	1,063	1,544	634	2,661	2,107	913	562	244
General and administrative expenses	2,317	1,116	2,014	2,507	2,254	3,517	601	938
	<u>3,380</u>	<u>2,660</u>	<u>2,648</u>	<u>5,168</u>	<u>4,361</u>	<u>4,430</u>	<u>1,163</u>	<u>1,182</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data**NOTE 14:- SUBSEQUENT EVENTS**

On February 12, 2019, in a follow-on underwritten public offering the Company sold an aggregate of 1,889,000 each consisting of (i) one ADS, and (ii) one warrant to purchase one ADS, at a public offering price of \$1.50 per unit, and (b) 2,444,800 pre-funded units, each consisting of (i) one pre-funded to purchase one ADS, and (ii) one warrant, at a public offering price of \$1.49 per pre-funded unit, resulting in gross proceeds of approximately NIS 25,508 (NIS 22,122 net of all issuance costs) including exercise by underwriters. In connection with the offering, the Company granted the underwriters a 45-day option to purchase up to an additional 650,070 ADSs and/or 650,070 warrants to purchase up to an additional 650,070 ADSs. The underwriters partially exercised their over-allotment option to purchase an aggregate of 350,000 additional ADS and additional warrants to purchase 650,070 ADSs. Subsequently, of the pre-funded warrants issued, we issued 2,444,650 ADSs upon exercise of pre-funded warrants. The Company paid approximately \$933 in offering fees and expenses.

Subsidiaries of Collect Biotechnology Ltd.

The following table sets forth the name and jurisdiction of incorporation of our significant subsidiary as of the date hereof.

Name of Subsidiary	Jurisdiction of Incorporation
Collect Biotherapeutics Ltd.	Israel

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Shai Yarkoni, certify that:

1. I have reviewed this Annual Report on Form 20-F of Collect Biotechnology Ltd. (the "Company");
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:
 - (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 18, 2019

/s/ Shai Yarkoni

Shai Yarkoni

Chief Executive Officer

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Eyal Leibovitz, certify that:

1. I have reviewed this Annual Report on Form 20-F of Collect Biotechnology Ltd. (the "Company");
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:
 - (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 18, 2019

/s/ Eyal Leibovitz

Eyal Leibovitz

Chief Financial Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350**

In connection with the filing of the Annual Report on Form 20-F for the period ended December 31, 2018 (the "Report") by Collect Biotechnology Ltd. (the "Company"), the undersigned, as Chief Executive Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

Date: March 18, 2019

/s/ Shai Yarkoni

Name: Shai Yarkoni

Title: Chief Executive Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350**

In connection with the filing of the Annual Report on Form 20-F for the period ended December 31, 2018 (the "Report") by Collect Biotechnology Ltd. (the "Company"), the undersigned, as Chief Financial Officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

Date: March 18, 2019

/s/ Eyal Leibovitz

Name: Eyal Leibovitz

Title: Chief Financial Officer

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Registration No. 333-214817, 333-220015 and 333-225003) and Form F-3 (333-212432 and 333-219614), of our report dated March 18, 2019, with respect to the consolidated financial statements of Collect Biotechnology Ltd. (formerly: Collect Biomed Ltd.), which appear in this Annual Report on Form 20-F for the year ended December 31, 2018.

Tel Aviv, Israel
March 18, 2019

/s/ Kost Forer Gabbay & Kasierer
KOST FORER GABBAY & KASIERER
A member of Ernst & Young Global