

**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, 2016

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

**23 Hata'as Street  
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**State of Israel**

(Jurisdiction of incorporation or organization)

(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 March 20, 2017: 107,583,485 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 or a non-accelerated filer.

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

Yes  No

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## INTRODUCTION

Collect is an emerging biotechnology company that is developing a novel technology platform known as Powered by Collect that functionally selects stem cells from a mixed population of cells in order to improve the safety and efficacy of regenerative medicine 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, physicians practicing regenerative medicine, and for researchers and academia engaged in stem cell research.

Our Ordinary Shares, or Ordinary Shares, are listed on the Tel Aviv Stock Exchange, or TASE, under the symbol “CLBD.” On July 29, 2016, our American Depositary Shares, or ADSs, each representing twenty of our Ordinary Shares, and our warrants, commenced trading on the NASDAQ Capital Market under the symbols “APOP” and “APOPW”, respectively.

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, par value of NIS 0.1 per share. We report financial information under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board 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, 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, and U.S. dollar translations of NIS amounts presented in this annual report on Form 20-F for the year ended on December 31, 2015 are translated using the rate of NIS 3.902 to \$1.00, the exchange rate reported by the Bank of Israel on December 31, 2015.

### 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:

- the overall global economic environment;
- the impact of competition and new technologies;

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- general market, political and economic conditions in the countries in which we operate;
- projected capital expenditures and liquidity;
- changes in our strategy;
- litigation; 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

## 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 statement of profit or loss and other comprehensive income data for fiscal years 2016, 2015 and 2014, and the selected consolidated financial position data at December 31, 2016, 2015 and 2014, 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 financial data should be read in conjunction with our consolidated financial statements, and are qualified entirely by reference to such consolidated financial statements.

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## Statement of comprehensive loss data

	Year ended December 31,			Convenience translation Year ended December 31,
	2014	2015	2016	2016
	NIS In Thousands except shares and share data			U.S. dollars in thousands
Research and development expenses	3,058	5,893	8,256	2,147
General and administrative expenses	2,491	4,204	7,968	2,072
Other Income	-	-	(280)	(73)
Total operating expenses	5,549	10,097	15,944	4,146
Operating loss	5,549	10,097	15,944	4,146
Financial income	(37)	(4)	(660)	(172)
Financial expenses	39	79	33	9
Net loss	5,551	10,172	15,317	3,983
Total Comprehensive loss	5,551	10,172	15,317	3,983
<b>Loss per share</b>				
Basic and diluted loss per share	0.084	0.137	0.168	0.044
Weighted average number of shares outstanding used to compute basic and diluted loss per share	65,968,768	74,475,109	91,128,516	91,128,516

## Statement of financial position

	December 31,		Convenience translation (Note 2d) December 31,
	2015	2016	2016
	NIS In Thousands		U.S. dollars in thousands
Cash and cash equivalents	3,913	6,279	1,633
Sort term deposits	-	19,660	5,113
Marketable securities	7,829	4,997	1,300
Other receivables	412	1,461	380
Restricted cash	20	140	36
Property, plant and equipment	1,187	1,373	357
Total assets	13,361	33,910	8,819
Trade payable	466	1,401	364
Other payables	2,394	2,084	542
Traded Warrants to ADS	-	1,938	504
Total liabilities	2,860	5,423	1,410
Total shareholders' equity	10,501	28,487	7,409

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The following table sets forth the high and low daily representative exchange rates for the NIS to \$1 U.S. dollar as reported by the Bank of Israel for each of the prior six months.

Month	NIS per U.S. dollars			Period End
	High	Low	Average	
February 2017	3.768	3.659	3.729	3.659
January 2017	3.860	3.769	3.818	3.769
December 2016	3.867	3.787	3.829	3.845
November 2016	3.876	3.799	3.843	3.839

October 2016	3.856	3.778	3.822	3.849
September 2016	3.786	3.746	3.766	3.758

## 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 technology, which we refer to as Powered by Collect, 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 Powered by Collect 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 Powered by Collect, and our business may fail.

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#### *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 Powered by Collect 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 on July 29, 2016) and have incurred losses in each year since our inception. We have historically incurred substantial net losses, including net losses of approximately NIS 15.3 million (\$4.0 million) in 2016, NIS 10.2 million (\$2.6 million) in 2015, NIS 5.5 million (\$1.4 million) in 2014, and NIS 3.7 million (\$1.0 million) in 2013. As of December 31, 2016, we had an accumulated deficit of approximately NIS 35.8 million (\$9.5 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, 2016 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 Apotainer™ kits;
- implement internal systems and infrastructures;
- seek to license additional technologies to develop;
- hire management and other personnel; and
- move towards commercialization.

#### *We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.*

As of December 31, 2016, we had approximately NIS 31.0 million (\$8.0 million) in cash and cash equivalents including marketable securities and short term deposits, a working capital of NIS 28.9 million (\$7.5 million) and an accumulated deficit of NIS 35.7 million (\$9.5 million). As of December 31, 2016, we had sufficient cash and cash deposits to fund operations through the end of the first quarter of 2018 if we do not raise additional capital. Since our inception, most of our resources have been dedicated to the development of Powered by Collect. In particular, we have expended and believe that we will continue to expend significant operating and capital expenditures for the foreseeable future developing our Powered by Collect 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 Powered by Collect 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 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 Powered by Collect technology platform;
- the scope, progress, results and costs of researching and developing our Powered by Collect technology platform and any future products, and conducting preclinical and clinical trials;

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- 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 Powered by Collect 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 Powered by Collect technology platform, our Apotainer™ collection kits or any future products.

***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 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 Powered by Collect 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 Powered by Collect 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 Powered by Collect 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 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 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 Food and Drug Administration (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 Powered by Collect 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 Hematopoietic stem cell transplantation ("HSCT") as a combination product subject to the primary jurisdiction of The Center for Devices and Radiological Health ("CDRH"), which is likely to result in the regulatory path usually followed for medical devices, which generally has less burdensome and costly requirements than the requirements for approval of a drug or biologic. 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. While we have had informal discussions with the FDA concerning our regulatory plans, we cannot assure you that the FDA would classify our Apotainer™ selection kits as a combination product subject to the primary jurisdiction of the CDRH that may qualify for the medical devices approval pathway. If the FDA were to classify our Apotainer™ selection kits as 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 jurisdiction, or were to prospectively alter the requirements for obtaining approval, the FDA could require us to meet more burdensome and lengthy approval requirements. Even if such approval could be obtained, we would be subject to more stringent level of post-market regulation as well. If any of these events were to occur, our financial condition and results of operations and cash flows could be materially and adversely affected.

***Clinical trials necessary to support approval for our Apotainer™ selection kits or any future products based on Powered by Collect technology platform would be 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 would prevent us from commercializing our Apotainer™ selection kits or any future product and could adversely affect our business,***

Initiating and completing clinical trials necessary to support approval for our Apotainer™ selection kits or any future products based on our Powered by Collect technology platform 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, would be time consuming and expensive with an uncertain outcome. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical trials could require the enrollment of large numbers of patients, and suitable patients could be difficult to identify and recruit. 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 Powered by Collect 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, they may not be commercially successful. Our Apotainer™ selection kits 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 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.***

We may seek to obtain an orphan designation for our Collect lead product in the U.S. 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 ("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 Powered by Collect 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.

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***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 apoptosis 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 believe that we will be able to obtain a sufficient supply of FasL for our needs in the foreseeable future, although we do not have a supply agreement in place. 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 we would not be able to manufacture our product candidates until a qualified alternative supplier is identified. Although alternative sources of supply exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers. Any significant delay in the supply of a product candidate or its key materials for a preclinical or clinical trial could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these 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.

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***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 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.

***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 executive officers, our management team 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, and Dr. Yaron Pereg, our Chief Development 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 annual report, 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 Powered by Collect 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 Powered by Collect 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 Powered by Collect 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 Powered by Celect technology platform, our Apotainer<sup>TM</sup> 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<sup>TM</sup> 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 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

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<sup>TM</sup> 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 Collect technology platform, our Apotainer<sup>TM</sup> 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.

***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. Our officers and most 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 has 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.

***Investors 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.***

None of our directors or officers are residents of the United States. 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 benefiting 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

***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 officer 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. See “Board Practices — Approval of Related Party Transactions under Israeli Law.” 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. 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.

***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 the Ownership of Our ADSs or Warrants or Ordinary Shares**

***Sales of a substantial number of our ADSs or Ordinary Shares or Warrants in the public market by our existing shareholders could cause our share price to fall.***

Sales of a substantial number of our ADSs or Ordinary Shares or warrants in the public market, or the perception that these sales might occur, could depress the market price of our ADSs or Ordinary Shares and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our ADSs or Ordinary Shares or warrants.

***If we were to be characterized as a PFIC for U.S. tax purposes, U.S. holders of our ADSs could have adverse U.S. income tax consequences.***

If we were to be characterized as a PFIC under the U.S. Internal Revenue Code of 1986, as amended, or the Code, in any taxable year during which a U.S. taxpayer owns ADSs, 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 the ADSs, whether or not we continue to be a PFIC. Based on the nature of our business, the projected composition of our income and the projected composition and estimated fair market values of our assets, we may be classified as a PFIC. In addition, we may have been a PFIC in prior years and may be a PFIC in the future. U.S. Holders who hold Ordinary Shares 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 QEF or mark-to-market election. A U.S. investor may be able to mitigate some of the adverse U.S. federal income tax consequences with respect to owning the ADSs for our taxable year ending December 31, 2016, provided that such U.S. investor is eligible to make, and successfully makes, a “mark-to-market” election. U.S. investors 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. 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 ADSs in the event we that qualify as a PFIC. For more information see “Taxation — U.S. Federal Income Tax

***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 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 issuer” 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 will be permitted, and intend, 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 intend to follow home country practice in Israel with regard to, among other things, board of directors independence requirements, director nomination procedures and quorum requirements. In addition, we may 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 also intend to follow our home country rules regarding the periodic approval of and changes to the formal charter for our compensation committee instead of the listing rules of NASDAQ. 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. See Item 16.G. “CORPORATE GOVERNANCE”

***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 warrants, or provide more favorable relative recommendations about our competitors, the price of the ADSs or 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 warrants or their trading volume.

***The market price for the ADSs and warrants may be volatile.***

The market price for the ADSs and 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.

***Our ordinary shares, the ADSs and warrants are traded on different markets and this may result in price variations.***

Our ordinary shares have been traded on the TASE since 1990. Our ADSs and warrants have been traded on NASDAQ since July 29, 2016. Trading in these securities on these markets take place in different currencies (dollars on NASDAQ and NIS on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Israel). The trading prices of our securities on these two markets may differ due to these and other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

***We have publicly announced our intention to delist our ordinary shares from the TASE which may result holders of our ordinary shares having difficulty disposing of their shares.***

We have publicly announced our intention to delist our ordinary shares that currently trade on the TASE, subject to various approvals, including shareholder approval. If we are successful in delisting our ordinary shares from the TASE, holders of our ordinary shares may have difficulty disposing of their ordinary shares in the absence of an active trading market.

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

Substantial sales of our ordinary shares, ADSs or warrants, either on the TASE or on NASDAQ, as applicable, may cause the market price of our ordinary shares, ADSs and warrants to decline. Almost all of our outstanding ordinary shares are registered and available for sale in Israel. Sales by us or our security holders of substantial amounts of our ordinary shares, ADSs or warrants, or the perception that these sales may occur in the future, could cause a reduction in the market price of our ordinary shares, ADSs or 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 ordinary shares or the ADSs or 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 the ADSs or ordinary shares, or investors who exercise the 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. Since 1990, our Ordinary Shares have been traded on the TASE in Israel, under the symbol “CLBD.” On July 29, 2016, our ADSs and warrants, commenced trading on the NASDAQ Capital Market under the symbols “APOP” and “APOPW”, respectively.

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. As a result of the merger, which closed on July 1, 2013, Collect Biotherapeutics became a fully 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](http://www.collect.co). None of the information on our website is incorporated by reference herein. Vcorp Services, LLC is our agent in the United States, and its address is 25 Robert Pitt Drive, Suite 204 Monsey, New York 10952.

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 could remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement under the Securities Act, (b) in which we have total annual gross revenue of at least \$1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Ordinary Shares that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We are a foreign private issuer as defined by 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 Stock 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 2016, 2015 and 2014 amounted to NIS 0.6 million (approximately \$0.15 million), NIS 1.0 million (approximately \$0.26 million) and NIS 0.2 million (approximately \$0.06 million), respectively. Our purchases of fixed assets primarily include laboratory equipment used for the development of our clinical treatment and for Leasehold improvements due to rent of new offices as our company grows. We financed these expenditures primarily from cash on hand.

#### *Recent Developments*

On February 14, 2017, we announced that we intend to file a petition with the Israeli court to voluntarily delist our ordinary shares from the Tel-Aviv Stock Exchange in accordance with Section 350 of the Israeli Companies Law. Such delisting is dependent on a number of factors, including obtaining the approval of our ordinary shareholders.

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On March 14, 2017, the district court of Tel Aviv (the “Court”) granted our request for the convening of a Special General Meeting of our shareholders for the purpose of (i) approving the extension of the expiration date of our Series-1 Stock Options (the “Series-1 Stock Options”) to a date that is 80 days from the Court’s approval for such extension, if granted (the Court had previously extended the expiration date of the Series-1 Stock Options to June 30, 2017), (ii) to amend the exercise price of the Series-1 Stock Options from NIS 1.85 to NIS 1.20 and (iii) requesting shareholder approval for the proposed delisting of our ordinary shares from the Tel Aviv Stock Exchange.

In addition, the Court granted our request for the convening of a Special General Meeting of the holders of our Series-1 Stock Options for the purpose of (i) approving the extension of the expiration date of the Series-1 Stock Options to a date that is 80 days from the Court’s approval for such extension, if granted, and (ii) to amend the exercise price of the Series-1 Stock Options from NIS 1.85 to NIS 1.20.

We intend to act promptly to convene the Special General Meeting of our shareholders and a Special General Meeting of the holders of our Series-1 Stock Options.

#### **B. Business Overview**

We are an emerging biotechnology company that has developed a novel technology platform known as Powered by Collect 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.

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 eliminating 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 Powered by Collect 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 maintenance 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 Powered by Collect technology platform, the Apotainer™ selection kit. The Apotainer™ selection kit is an easy to use, cost effective, off the shelf stem cell selection kit. The kit proof of efficacy is tested in clinical use in allogeneic (using stem cells from a donor) 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 high toxicity. However, application of allogeneic HSCT is limited by GvHD, a condition in which the transplanted immune cells (populating the graft in 10,000 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 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 recurrence and high costs of treatment.

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We have chosen allogeneic HSCT for the treatment of hematological malignancies as our first target indication for our Powered by Collect 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 Powered by Collect technology platform for the treatment of other indications (e.g., solid organ transplantation and auto-immune diseases) and consequently for the adoption of our Powered by Collect 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 permitting us to further develop our technology for multiple indications, even 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 Powered by Collect technology platform in the near term.

We plan to bring our Apotainer™ selection kits to market for HSCT as a combination product subject to the primary jurisdiction of the CBER, which is likely to result in the regulatory path usually followed for medical devices. The term “combination product”, when used to describe our Apotainer™ selection kits, refers to a product, regulated by the FDA, which is comprised of a consumable medical device (container) with a biological activity. We believe that our Apotainer™ selection kit will be designated as an orphan product and possibly a 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.

All of our research efforts to date have culminated in two studies performed on human HSCT grafts. The first study was performed during 2015 - 2016. In this study we used small portions of a graft to validate and optimize the process, and show robustness and repeatability of the process. More than 100 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 forming). Some of these samples were transplanted into murine models for safety and GvHD assessments. Results from this study are planned to be published in an upcoming medical conference. The second study, which was initiated in the first quarter of 2017, is performed on cancer patients undergoing matched related HSCT transplantation. This Phase I/II trial was approved by the Israeli Ministry of Health and the Rambam Medical Center’s ethical committee. The first patient was

Consequently, we hope to commence a second human trial in the United States and/or Europe in the first half of 2018. We plan on holding a pre-Investigational New Drug ("IND") meeting with the FDA during H1-2017 and hopefully initiate USFDA study before the end of 2017. We hope to initiate a pivotal study in 2018-2019.

## Our Strategy

We have developed a novel technology platform, the Powered by Collect technology platform, for the functional selection of adult stem cells. This technology is expected to improve the safety and efficacy of regenerative medicine and stem cell therapies by 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 Powered by Collect technology platform in a clinical setting.** We have chosen allogeneic HSCT for the treatment of hematological malignancies as our first target indication for our Powered by Collect 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 Powered by Collect 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, combination products obtain relatively quick validation from the FDA and the EMA when compared to pharmaceutical/ biological products and drugs. 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 small number of patients (approximately one hundred in total) in order to obtain marketing approval of our Apotainer™ product. We believe such a study can be completed in approximately four to five years. However, there is no guarantee that the proposed pathway will be approved by the FDA or EMA, or that validation will occur as quickly as we hope, if at all. In addition, we believe that our product may achieve either "breakthrough" or orphan drug designation with the FDA, enabling a fast track review and approval process by the FDA. 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.

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- **Leverage our scientific, clinical and regulatory expertise to build and advance our Powered by Collect 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 test the kit for solid organ transplantation and auto-immune system disorders (such as Type 1 diabetes, Crohn's disease, psoriasis and lupus). We also intend to develop our Powered by Collect 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 Powered by Collect technology platform.
- **Build a diversified product portfolio.** Beginning with the development of our Apotainer™ selection kit as a combined product or 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 Powered by Collect 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 Powered by Collect 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 Powered by Collect 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 Powered by Collect 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. We intend to launch a proactive campaign for engaging those companies during 2017.

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

- **Pathway to first-in-human proof of concept:** We are currently enrolling patients to a phase I/II performed on cancer patients undergoing matched related transplantation. This Phase I/II trial was approved by the Israeli Ministry of Health and the Rambam Medical Center's ethical committee. First patient was recruited on February 6, 2017 and interim results are expected during the second half of 2017. We also plan to meet with the FDA for a pre-IND meeting during the first half of 2017.
- **Pathway to product prototype:** We are engaged in developing prototypes of our Apotainer™ selection kit. Recently, we demonstrated a proof of concept for the binding of the apoptotic protein to a polymer without impairing 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. We aim to complete development of the prototype Apotainer™ selection kit by the end of 2017.

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- **Patent portfolio enhancement:** We are currently expanding our patent coverage from our current seven patent families by applying for additional patents for inventions created during the development. 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 Regenerative Medicine (2008, 3(1), 1-5 [47]), 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 third-party 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' cells is severely limited by the immune system of the patient which may reject the transplanted cells. 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, third-party 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 serums 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 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.

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. 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.

#### Market for Cell-Based Therapies

According to a 2015 report by Visiongain, the world stem cell technologies market is expected to grow from \$7.2 billion in 2014 to \$12 billion in 2018, achieving high revenue growth from 2015 to 2025.

- **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.
- **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, the stem cell and progenitor therapy market raised \$2.6 billion in public and private funds in 2014, while according to the National Institutes of Health, or NIH, the level of annual support for stem cell research across the NIH is estimated to grow from \$1.179 billion in 2011 to \$1.436 billion in 2016.

The following table from the 2015 Report of the Alliance for Regenerative Medicine illustrates the wide range of indications being targeted by the stem cell product pipeline:

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#### Our Current Focus: Proof of Concept of our Powered by Cellect technology platform through the treatment of Haematological Malignancies

Haematological 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 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. Despite improved prophylactic regimens, acute GvHD disease still occurs in 26% to 34% of recipients of full matched sibling donor grafts, and in 42% to 52% of recipients of matched unrelated donor grafts (Center for International Blood and Marrow Transplant Research, last accessed 30 August 2016). The incidence of chronic GvHD ranges from 20% to 70% of recipients of allogeneic HCT, and is increasing due to the increased number of allogeneic HSCT survivors, older recipient age, use of alternative donor grafts, and use of peripheral blood stem cells. GvHD accounts for 15% of deaths after allogeneic HSCT (Pérez-Simón JA, et al., 2008), and is the leading cause of non-relapse mortality (NRM) after allogeneic HSCT. 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 Powered by Collect 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 platform technology.

## **An Unmet Need: Efficient Stem Cell Selection**

Typically, there is a very small number of stem cells in the source tissue (1 in 10,000 cells in bone marrow, the tissue with the highest stem cell concentration) 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 that contribute to engraftment failure, 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 cells 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 Powered by Collect 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 Powered by Collect technology platform is allogeneic HSCT for hematological malignancies. According to the Center for International Blood & Marrow Transplant Research, over 6,000 allogeneic HSCTs were performed in the United States in 2012 for these two diseases. 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 leukemias and for lymphoma. We believe that beyond the value of proving and validating our platform technology, these numbers represent a substantial market opportunity for us to prove the benefits of our Powered by Collect technology platform.

## **Our Proprietary Stem Cell Technology Platform**

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

stem cells, we 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 at the same time eliminating apoptosis sensitive mature immune cells. We believe this will result in a reduction of GvHD, improved graft acceptance and a reduction in treatment cost.

### The ApoGraft Process

To achieve functional selection of stem cells utilizing our Powered by Collect 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 immediately 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 factor family. The binding of FasL with its receptor induces apoptosis (programmed cell death) that plays an important role in the development, homeostasis, and function of the immune system.

The apoptotic inducer used in Collect's ApoGraft process is based on a FasL protein known by its commercial name Apo010. Apo010 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.

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The ApoGraft process is illustrated below:

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### Apotainer™ Selection Kit

Our first product that is currently being developed, the Apotainer™ selection kit, is an easy to use, cost effective, off the shelf stem cell selection kit for clinical laboratories designed to improve the results of human allogeneic HSCT.

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The Apotainer™ selection kit is a specialized infusion bag which its inner surface is coated with FasL. The Apotainer™ selection kit is designed to create a microenvironment intended to induce apoptosis by creating an ex-vivo microenvironment that resembles 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.

Our preclinical research has shown that FasL appears to be active when immobilized, as in the case of its binding to the film of the Apotainer™ selection kit. This immobilization to the kit also creates another advantage by eliminating the need to discard the FasL from the graft before transplantation.

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 surface-bound FasL and undergo apoptosis while the hematopoietic stem cells remain active. 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.

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### Preclinical Studies

As part of our in-vitro studies, and prior to animal studies, we performed studies to determine which apoptotic molecules have the best differential effect on stem and non-stem cells. We have conducted eleven animal studies including murine to murine and human cells to murine transplantation models measuring the relevant effects (GvHD, 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;
- Preservation of stem and progenitor cells;
- Preservation of successful engraftment (95% engraftment by Contract Research Organization);
- 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.

We also achieved an important milestone in the development of our stem cell selection kits: proof of feasibility that our apoptosis-inducing protein can be bound to surfaces without compromising the biological activity of the protein. Trials that were conducted in cooperation with American and Israeli partners, including Entegris, University of Louisville, Bar-Ilan University and the Israel Center for Plastics and Rubber, showed that on some of the plastic surfaces tested, the bound protein induced apoptosis in the same manner as it had in previous experiments in which the protein was unbound.

In June 2015, we entered into a Joint Product Development Agreement with Entegris Inc., or Entegris (NASDAQ: ENTG), a provider of yield-enhancing materials and solutions for advanced manufacturing processes, or the Entegris Agreement. Under the Entegris Agreement, the parties are collaborating in the development of the polymer film that will be used for the manufacturing of the Apotainer™ selection kit. The Entegris Agreement contemplates that upon successful development of the polymer film, Entegris will supply the polymer film upon terms to be agreed to between the parties at such time. The parties agree that if Entegris defaults in this obligation, the Company may find an alternate party for manufacturing the polymer system, in which case Entegris would be entitled to 5% of final product sales up to the amount paid by Entegris. Pursuant to the terms of the Entegris Agreement, Entegris shall bear all costs relating to the development, design, engineering and manufacture of polymer systems relating to the development of the product and we will bear the costs relating to the pre-clinical development of the product. In addition, the parties have agreed to complete one or more statements of work, or a SOW, each of which may set forth the terms for the objectives, timelines and costs and time estimates for each milestone. The Entegris Agreement has a term of five years, unless earlier terminated, and automatically renews for successive one year terms. Either we or Entegris may terminate the Entegris Agreement for cause if either party materially breaches the agreement or a SOW thereunder and the breaching party fails to cure within ten days notice of a breach, in the event of a monetary breach, or thirty days from receipt of notice of a breach, in the event of a non-monetary breach. Additionally, either party may terminate the Entegris Agreement or any SOW immediately upon written notice of the non-terminating party if a petition for bankruptcy is filed, whether voluntarily or involuntarily, and such petition is not dismissed with prejudice within sixty days of its filing.

On June 14, 2016, we were advised that we were eligible for an award consisting of a \$0.9 million (approximately NIS 3.5 million) conditional grant by the BIRD Foundation in support of our Joint Product Development Agreement with Entegris. The BIRD Foundation promotes collaboration between U.S. and Israeli companies in various technological fields for the purpose of joint product development. Projects submitted to the BIRD Foundation are reviewed by evaluators appointed by the National Institute of Standards and Technology (NIST) and by the Israel Innovation Authority of the Israeli Ministry of Economy and Industry. The grant is dependent on the execution of a Cooperation and Project Funding Agreement, or CPFA, by and among the BIRD Foundation, Entegris and us, which we are required to execute by September 14, 2016, and which we received an extension until March 17, 2017. We are in the process of finalizing and executed a negotiated CPFA with the BIRD Foundation and Entegris, although there is no guarantee we will be successful in doing so. Pursuant to the terms of the negotiated CPFA, the BIRD Foundation will provide a grant to Entegris and us of up to \$0.9 million. Pursuant to the terms of the CPFA, we and Entegris will be required to repay the total sum of the grant, linked to the U.S. Consumer Price Index from date of receipt of each payment, of 100%, 113%, 125%, 138% and 150% of the linked sum granted by the BIRD Foundation if repaid within one year, two years, three years, four years and five or more years, respectively, of the project completion date. The CPFA will also require that we and Entegris commence repayments at the rate of 5% of each dollar reported as revenue derived from the product, or subsequent products, funded by the project. In addition, the CPFA will include a requirement that if the funded product is licensed to a third party 30% of all payments received under the respective license agreement must be paid to the BIRD Foundation in repayment of the grant. Finally, the CPFA will include a requirement that if any portion of the product funded by the project is sold outright to a third party prior to full repayment of the grant to the BIRD Foundation, one-half of the sale proceeds will be applied to the repayment of the grant.

In August 2015, we initiated a full preclinical Good Laboratory Practice safety study designed to test safety and engraftment outcome in a murine model ahead of our first planned clinical trial. Complete clinical, biochemical and histology evaluation is being performed by a contract research organization. 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.

On April 19, 2016, we entered into a collaboration agreement with Accellta Ltd., or Accellta, whereby Accellta will receive a non-exclusive right to evaluate the impact of our apoptotic induction based technology on Accellta's stem cell culturing technologies. The objective of the collaboration with Accellta is to assess the impact of our technology which is based on apoptosis-inducing agents on Accellta's induced pluripotent stem cell technology. In consideration of the limited right to test our technology, Accellta has agreed to pay us \$75,000. Upon conclusion of the evaluation period, the parties will negotiate, in good faith, the terms of a limited license agreement for our technology, restricted to research only cell technology.

On September 12, 2016, we obtained the approval of the Israeli Ministry of Health to initiate a Phase I/II, single arm, open label clinical trial 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 study is conducted in Rambam Medical Center in Haifa, Israel. We expect that the length of the phase I/II, single arm, open label clinical trial will be approximately 18 months. In the study, the graft will be taken from the donor through regularly used apheresis and then the cells will be exposed to short incubation with FasL and then undergo washing and centrifugation to remove the FasL. The resulting cells will then be transfused to the patient according to routine myeloablative procedures, or therapeutic modalities, including, but not limited to, chemotherapy, radiotherapy and immunotherapy. We expect to enroll up to 12 patients with various hematological malignancies in need of allogeneic HSCT. The primary endpoint is expected to be safety and the secondary endpoint is expected to be efficacy measures including incidence of acute GvHD at day 100.

The study is conducted in a tertiary bone marrow transplant center in Israel. To that end we entered into an agreement with the Rambam Medical Center in Haifa, Israel for the purpose of conducting a clinical trial under approval from the local Institutional Review Board and Israeli Ministry of Health at the medical center.

On February 2, 2017 we announced that the first blood cancer patient has been treated in this Phase I/II trial.

On February 21, 2017 we announced positive final results from a non-interventional clinical trial of ApoGraft™ in healthy donors. The study's primary objective was to validate the Company's proprietary method of stem cell selection by going through the process of production and characterization with ApoGraft™, and was conducted on samples obtained in collaboration with two medical centers in Israel, The Schneider Children's Medical Center and the Rambam Medical Center. The study included samples from 104 healthy donors of blood stem cells. The samples (collected under approval of Helsinki committees) represented 5% of a graft used for transplantation into patients. The cells were exposed to the full process of preparing the ApoGraft. The grafts were processed allowing stem cell production for

transplantation with Collect's ApoGraft™. The use of the ApoGraft™ resulted in a significant increase in the death of mature immune cells, primarily T lymphocytes, without compromising the quantity and quality of stem cells. The results have shown that the procedure is highly repetitive. The acceptance criteria and batch release criteria were all set and met. Samples have shown sterility and viability of cells within specs. T cells have shown apoptotic effect while CD34 stem cells were intact. Clonality was not compromised. The overall results were highly correlated with the safety studies performed as part of the pre-clinical package and supports the Phase I/II HSCT in blood cancers patients.

#### *Future Studies*

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

- Conduct the ongoing Phase I/II ApoGraft clinical trial;
- Complete the development of the first prototype of the Apotainer™ selection kits;
- Develop sterilization methods and Apotainer™ selection kits shelf life;
- Produce initial batches of the Apotainer™ selection kits for clinical trials;
- Meet FDA and/or European regulatory authorities and submit a trial protocol for a clinical trial using the Apotainer™ selection kit;
- Prepare for second indication trial; and
- Establish FasL effect on fat derived stem cells in an animal study.

#### *Regulatory Status*

Our stem cell kits are still under development, and to date we have conducted only animal studies and other preclinical work with respect to our technology platform. We have not made any filing with any regulatory authority, other than to applications to support the ongoing and completed clinical trials, seeking approval or clearance for our Powered by Collect technology platform or our Apotainer™ selection kits.

Based on the views of our scientific advisors and following informal discussions with U.S. and European regulatory authorities, we intend to seek regulatory approval of our stem cell kits that we are developing in the United States, Europe and other countries as a combined therapy or Class III "medical device". We believe that being classified as a medical device as opposed to a medicinal product will result in cost savings and reduce time to market.

#### *Future Applications*

Beyond the use of our Powered by Collect 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 auto-immune 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 diabetes (Type i), lupus, 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 Powered by Collect 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.
- Develop the use of Fat derived mesenchymal stem cells under FasL treatment for various indications including immune tolerance, orthopedic and dermatologic indications.

#### **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 are focused on additional animal models of a variety of diseases, experiments to determine the mechanism of action of our Powered by Collect technology platform, and toxicology testing. Based on these preclinical programs we have began clinical testing of products based on our Powered by Collect technology platform in humans. During the years ended December 31, 2014, 2015 and 2016, we incurred \$0.9 million, \$1.5 million and \$2.1 million, respectively (based on the average of NIS/USD exchange rates reported by the Bank of Israel for each of the three years ended on these respective dates: 2014 – 3.578, 2015 – 3.887, 2016 – 3.84) in expenses on company-sponsored research and development activities.



## Raw Materials and Suppliers

Although most raw materials for the Apotainer™ selection kits we are developing are readily obtainable from multiple sources, we know of only two manufacturers of FasL (the apoptotic inducing signal), Oncology Ventures A/S, or Oncology Ventures, and Adipogen International. We currently rely on Oncology Ventures as our sole source supplier for FasL and Oncology Ventures has provided us with the relevant FasL materials for our phase I/II trials conducted to date. We believe that we will be able to obtain a sufficient supply of FasL for our needs in the foreseeable future, although we do not have a supply agreement in place. Although alternative sources of supply exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers.

Any significant delay in the supply of key materials for a preclinical or clinical trial could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these 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 currently working with Entegris to jointly develop the polymer film that will be used for the manufacturing of the Apotainer™ selection kit and may engage Entegris in the future to manufacture the Apotainer™ selection kits for clinical and/or commercial purposes.

## 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 abroad. 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 by CD34) or deplete mature hematopoietic cells such as T cells from the biological sample (negative selection by monoclonal activity against T-cell receptor  $\alpha\beta$ ), 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 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., or Athersys, 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 Powered by Collect 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. The company received notice of allowance from the USPTO and expects issuance soon. The application is in national phase in Europe 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 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. If patents are issued from these applications, and if the appropriate maintenance fees are paid, these patents are currently expected to expire in March, 2033.
- A patent application entitled “Activation of Hematopoietic Progenitors by Pretansplant Exposure to Death Ligands” was filed as a PCT application and is now in national phase in Australia, Brazil, Canada, China, Europe, India, Israel, Japan, Korea, Russia 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 in June 2016. 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 in September 2016. 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 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 Combination Products***

The FDA has specified a definition for the term “combination product,” which includes: (1) a product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity; (2) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; (3) a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or (4) any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to

The FDA is divided into various “centers” by product type such as the Center for Drug Evaluation and Research, or CDER, the Center for Biologics Evaluation and Research, or CBER, or the CDRH. Different Centers typically review drug, biologic, or device applications. In order to review an application for a combination product, the FDA must decide which center should be the center with primary jurisdiction or the lead center for the review. FDA regulations require that the FDA determine the combination product’s primary mode of action which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The center that regulates that portion of the product that generates the primary mode of action becomes the lead evaluator. If there are two independent modes of action, neither of which is subordinate to the other, the FDA makes a determination as to which center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions or to the center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product. When evaluating an application, a lead center may consult other centers but still retain complete reviewing authority, or it may collaborate with another center, by which the center assigns review of a specific section of the application to another center, delegating its review authority for that section. Typically, the FDA requires a single marketing application submitted to the center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one center. One reason to submit multiple evaluations is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product exclusivity. If multiple applications are submitted, each may be evaluated by a different lead center.

Because we believe the primary mode of action for our Apotainer™ selection kits for HSCT is that of a medical device, we anticipate that when, and if, we apply for approval in the United States, our Apotainer™ selection kits will be reviewed by the FDA with CDRH having primary jurisdiction for review and regulation, which is likely to result in the regulatory path usually followed for medical devices. While we have had informal discussions with the FDA concerning our regulatory plans, we cannot assure you that the FDA would classify our Apotainer™ selection kits as a combination product primarily regulated by the CDRH that may qualify for the medical devices approval pathway. If the FDA were to classify our Apotainer™ selection kits as a drug, biologic or a combination product primarily subject to CDER or CBER jurisdiction, or were to prospectively alter the requirements for obtaining approval, the FDA could require us to meet more burdensome and lengthy approval requirements. Even if such approval could be obtained, we would be subject to more stringent level of post-market regulation as well.

### ***FDA Approval Process***

The FDA governs the following activities that we may perform or that may be performed on our behalf, to ensure that the medical devices 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;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

### ***FDA Premarket Clearance and Approval Requirements***

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either premarket notification, or 510(k) clearance, or approval of a premarket approval application, or PMA, from the FDA. 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.

We believe our Apotainer™ selection kits are likely to be considered as a Class III medical device requiring FDA approval of a PMA.

### ***510(k) Clearance Pathway***

When a 510(k) clearance is required, we will be 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.

### *PMA Approval Pathway*

A PMA 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 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. 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. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. 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.

### ***Pervasive and Continuing Regulation***

After a device is placed on the market, numerous regulatory requirements continue to apply. In addition to the requirements below, the Medical Device 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;

- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, 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 cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- 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 device;
- 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.

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 U.S. Public Health Service Act, 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.

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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.

While we do not currently intend to rely on the regulation of HCT/Ps under Part 1271, if we do so in the future, the FDA may disagree with this position or conclude that we do not meet the applicable definitions and exemptions to the regulation. If we are not regulated solely under the HCT/P provisions, we would need to expend significant resources to comply with the FDA's broad regulatory authority under the FDCA.

### ***Pharmaceutical 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 drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs 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 drugs 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 drugs. 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 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. European Union 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 drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert 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.

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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 Patient Protection and Affordable Care Act was enacted in the United States in March 2010 and contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. 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.

### ***Anti-kickback and false claims laws***

In addition to FDA restrictions on marketing of bio-pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the bio-pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute 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 bio-pharmaceutical manufacturers on the one hand and

prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute 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.

Federal false claims laws prohibit 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.

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#### **Foreign Regulatory Requirements**

International sales of medical devices 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.

The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Each European Union 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 European Union with respect to medical devices. Devices that comply with the requirements of the laws of the relevant member state applying the applicable European Union directive are entitled to bear a CE mark and, accordingly, can be distributed throughout the member states of the European Union as well as in other countries, such as Switzerland and Israel, that have mutual recognition agreements with the European Union or have adopted the European Union'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 European Union is required in order for a manufacturer to commercially distribute the device throughout the European Union. 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.

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#### **Sales and Marketing**

We intend to launch a business development campaign during 2017. Interim results from the ongoing Phase I/II study will establish safety profile of our Apograft and will validate our platform technology. These results will qualify our technology for out licensing to companies interested in improving their manufacturing process of adult tem- cells based products. To address these plans we intend to open up business development offices and hire a vice president for business development in United States. The recruitment of the team and the data from the clinical trials is expected to converge and allow the initiation of series of licenses on a non- exclusive basis to various stem cells based companies.

#### **C. Organizational Structure**

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

#### **D. Property, Plant and Equipment**

Our headquarters is currently located in Kfar Saba, Israel and consists of approximately 4,360 square feet of leased office space under a lease until October 14, 2020, with an option to terminate the agreement on October 14, 2018. In addition, we hold options to extend the lease period until October 14, 2022 and until October 14, 2024. 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 International Accounting Standards Board 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 period 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, and U.S. dollar translations of NIS amounts presented in this annual report on Form 20-F for the period ended on December 31, 2015 are translated using the rate of NIS 3.902 to \$1.00, the exchange rate reported by the Bank of Israel on December 31, 2015.

## 5.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, 2016, we had an accumulated deficit of NIS 35.7 million (approximately \$9.3 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.

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### Research and Development Expenses, net

Our research and development expenses consist primarily of salaries and related personnel expenses, subcontractor expenses, patent registration fees, materials, and other related research and development expenses.

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

	Year ended December 31,			
	2014	2015	2016	2016
	NIS			USD*
(in thousands)				
Payroll	1,555	2,739	3,711	966
Subcontractors	146	538	534	139
Patent registration	169	326	409	106
R&D related purchases	208	770	1,676	436
Share-based payment	512	523	253	66
Professional services	400	746	1,044	271
Other expenses	68	251	629	164
	<u>3,058</u>	<u>5,893</u>	<u>8,256</u>	<u>2,148</u>

\* USD presented as convenience translation using 31.12.16 NIS/USD rate of: 3.845 NIS.

### General and Administrative Expenses

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

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

	Year ended December 31,			
	2014	2015	2016	2016
	NIS			USD*
(in thousands)				
Payroll	850	1,024	2,994	779
Professional services	762	1,366	2,074	539
Director fees	269	358	318	83
Office expense	161	235	466	121
Share-based payment	286	795	1,299	338
Other expenses	163	426	817	212
Total	<u>2,491</u>	<u>4,204</u>	<u>7,968</u>	<u>2,072</u>

\* USD presented as convenience translation using 31.12.16 NIS/USD rate of: 3.845 NIS.

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## Comparison of the year ended December 31, 2016 to the year ended December 31, 2015 to the year ended December 31, 2014

### Results of Operations

	December 31,			December 31,		
	2014	2015	2016	2014*	2015*	2016*
	(in thousands of NIS)			(in thousands of USD)		
Research and development expenses, net	3,058	5,893	8,256	786	1,510	2,147
General and administrative expenses	2,491	4,204	7,968	640	1,077	2,072
Other income	-	-	(280)	-	-	(73)
Operating loss	<u>5,549</u>	<u>10,097</u>	<u>15,944</u>	<u>1,426</u>	<u>2,587</u>	<u>4,146</u>

	2	75	(627)	1	19	(163)
Finance expense (income), net						
Total comprehensive loss	5,551	10,172	15,317	1,427	2,606	3,983
Loss attributable to holders of Ordinary Shares	5,551	10,172	15,317	1,427	2,606	3,983

\* USD presented as convenience translation using year end 2016, 2015, 2014 NIS/USD rate of: 3.845 NIS, 3.902 NIS, 3.889 NIS respectively.

### **Research and Development Expenses, net**

Our research and development expenses for the year ended December 31, 2016 amounted to NIS 8.3 million (approximately \$2.1 million), representing an increase of NIS 2.4 million (approximately \$0.6 million), or 40%, compared to NIS 5.9 million (approximately \$1.5 million) for the year ended December 31, 2015. The increase was primarily attributable to an increase of NIS 1.2 million (approximately \$0.3 million) from R&D related expenses as part of the preparation for the clinical trial and for the lab and to an increase of salaries and related personnel expenses in an amount of NIS 1.0 million (approximately \$0.26 million) reflecting the growth in the company's activities resulting from an increase in the number of employees engaged in research and development related activities from nine to thirteen.

Our research and development expenses for the year ended December 31, 2015 amounted to NIS 5.9 million (approximately \$1.5 million) compared to NIS 3.0 million (approximately \$0.8 million) for the year ended December 31, 2014. The increase was primarily attributable to an increase of expenses related to third-party preclinical consultants and other expenses related to conducting preclinical trials in an amount of \$0.33 million and to an increase of salaries and related personnel expenses in an amount of \$0.27 million reflecting the growth in the company activities resulting from an increase in the number of employees engaged in research and development related activities from five to nine.

### **General and Administrative Expenses**

Our general and administrative expenses totaled NIS 8.0 million (approximately \$2.0 million) for the year ended December 31, 2016, an increase of NIS 3.7 million (approximately \$1.0 million), or 89%, compared to NIS 4.2 million (approximately \$1.0 million) for the year ended December 31, 2015. The increase resulted primarily from an increase of NIS 2.5 million (approximately \$0.65 million) in payroll and share based compensation reflecting the growth in the company activities resulting from an increase in the number of employees and an increase of NIS 0.7 million (approximately \$0.18) in professional services due to increase in legal and investor and public relations expenses after the IPO.

Our general and administrative expenses for the year ended December 31, 2015 amounted to NIS 4.2 million (\$1.0 million) compared to NIS 2.5 million (\$0.6 million) for the year ended December 31, 2014. The increase resulted primarily from an increase of \$0.13 million in share-based compensation expenses, an increase of payroll in an amount of \$0.03 million reflecting the growth in the company activities resulting from an increase of payroll to our employees, an increase of \$0.1 million in professional services and an increase of \$0.05 million in travel and conference expenses.

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### **Operating Loss**

As a result of the foregoing, our operating loss for the year ended December 31, 2016 was NIS 15.9 million (approximately \$4.1 million), as compared to an operating loss of NIS 10.1 million (approximately \$2.6 million) for the year ended December 31, 2015, an increase of NIS 5.9 million (approximately \$1.5 million), or 58%.

As a result of the foregoing, our operating loss for the year ended December 31, 2015 was NIS 10.1 million (approximately \$2.6 million), as compared to an operating loss of NIS 5.5 million (approximately \$1.4 million) for the year ended December 31, 2014, an increase of NIS 4.5 million (approximately \$1.2 million), or 82%.

### **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 that were provided to investors who participated in certain fund raising rounds, and exchange rate differences.

We recognized net financial income of NIS 0.6 million (approximately \$0.16 million) for the year ended December 31, 2016, compared to net financial expense of NIS 0.075 million (approximately \$0.02 million) for the year ended December 31, 2015. The increase is primarily due to the change in the fair value of the tradable warrant granted on the IPO.

We recognized financial expenses, net of NIS 0.075 million (\$0.02 million) for the year ended December 31, 2015 compared to financial expenses, net of NIS 0.002 (less than \$0.001 million) for the year ended December 31, 2014. Financial expenses, net in 2015 were derived mainly from revaluations of foreign-currency-linked cash balances.

### **Total Comprehensive Loss**

As a result of the foregoing, our loss for the year ended December 31, 2016 was NIS 15.3 million (approximately \$4.0 million), as compared to NIS 10.1 million (approximately \$2.6 million) for the year ended December 31, 2015, an increase of NIS 5.1 million (approximately \$1.3 million), or 51%.

As a result of the foregoing, our loss for the year ended December 31, 2015 was NIS 10.1 million (approximately \$2.6 million), as compared to NIS 5.5 million (approximately \$1.4 million) for the year ended December 31, 2014, an increase of NIS 4.6 million (approximately \$1.2 million), or 83%.

### **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.

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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 TASE and benchmarks of related companies.
- *Expected Term.* The expected term of options granted is based upon historical experience 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.

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## 5.B Liquidity and Capital Resources

### Overview

From January 2016 through December 31, 2016, we have funded our operations principally with NIS 40 million (approximately \$10.4 million) from the issuance of Ordinary Shares and warrants. As of December 31 2016, we had NIS 40 million (approximately \$8.0 million) in cash and cash equivalents including short term deposits and Marketable securities.

The table below presents our cash flows:

	Year ended December 31,					
	2014	2015	2016	2014*	2015*	2016*
	(in thousands of NIS)			(in thousands of USD)		
Operating activities	(4,399)	(7,710)	(14,412)	(1,131)	(1,975)	(3,748)
Investing activities	(11,451)	3,175	(18,012)	(2,944)	814	(4,684)
Financing activities	13,933	6,396	34,924	3,583	1,639	9,083
Net increase in cash and cash equivalents	(1,922)	1,791	2,366	(494)	459	615

\* USD presented as convenience translation using year end 2016, 2015, 2014 NIS/USD rate of: 3.845 NIS, 3.902 NIS, 3.889 NIS respectively.

### Operating Activities

Net cash used in operating activities was NIS 14.4 million (approximately \$3.7 million) for the year ended December 31, 2016, compared with net cash used in operating activities of approximately NIS 7.7 million (approximately \$2.0 million) for the year ended December 31, 2015. Compared with net cash used in operating activities was NIS 4.4 million (approximately \$1.1 million) for the year ended December 31, 2014, The increases in such periods are primarily due to increases in ongoing research costs and increases in the number of employees.

### Investing Activities

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

Net cash provided in investing activities of NIS 3.1 million (approximately \$0.8 million) during 2015 primarily reflects sales of Marketable securities measured at fair value through profit and loss.

Net cash used in investing activities of NIS 11.4 million (approximately \$2.9 million) during 2014 primarily reflects invest in Marketable securities measured at fair value through profit and loss.

### Financing Activities

Net cash provided by financing activities in the years ended December 31, 2016, 2015 and 2014 consisted of NIS 34.9 million (approximately \$9.1 million) and NIS 6.4 million (approximately \$1.6 million) and NIS 14.0 million (approximately \$3.6 million) respectively, of net proceeds, mainly from the issuance of ordinary shares 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 have an exercise price of NIS 2.1 (approximately \$0.54) per warrant. These warrants will expire in March 7, 2018.

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In July 29, 2016, we issued an aggregate of 1,292,308 ADS's (approximately 25,846,160 Ordinary Shares) pursuant to our initial public offering, at a price of \$6.5 per ADS.

### Current Outlook

We have financed our operations to date primarily through proceeds from issuance of our Ordinary Shares. We have incurred losses and generated negative cash flows from operations since July 2013. We have never generated any revenue from the sale of products and we do not expect to generate revenues from sale of our products until at least 2018.

We expect that our existing cash and cash equivalents will be sufficient to fund our current operations until at least the end of the first quarter of 2018, however, we expect that we will require substantial additional capital to support the mass production of our products.

In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future capital requirements will depend on many factors, including:

- the progress and costs of our research and development activities;
- the costs of manufacturing our Apograft product;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally; and
- the magnitude of our general and administrative expenses.

Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through debt or equity financing. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or commercialization efforts with respect to our products. This may raise substantial doubts about our ability to continue as a going concern.

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

See above, under Item 5A – “Operating Results”.

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### 5.D Trend Information

Not applicable

### 5.E Off-Balance Sheet Arrangements

We currently do not have any off-balance sheet arrangements.

### 5.F Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2016:

	Total	Less than 1 year	1-3 years (in thousands)	4-5 years	More than 5 years
Operating Lease Obligations in NIS	936	512	424	-	-
Operating Lease Obligations in \$	243	133	110	-	-

The contractual obligation in respect of government grants presented above is based on our estimation regarding expected revenues, thus there is no certainty that the liability will be settled in 1-3 years as stated above.

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

### A. Directors and Senior Management

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

Name	Age	Position
Kasbian Nuriel Chirich	59	Chairman of the Board of Directors
Dr. Shai Yarkoni	59	Chief Executive Officer and Director
Eyal Leibovitz	56	Chief Financial Officer
Yaron Pereg	43	Chief Development Officer
Dr. Amotz Nechushtan	57	Vice President of Research and Development
Abraham Nahmias <sup>(1)(2)(3)</sup>	62	Director
Dr. Ruth Ben Yakar	47	Director
Yuval Berman <sup>(1)(2)(3)</sup>	51	External Director
David Grossman <sup>(1)(2)(3)</sup>	42	External Director
Michael Berelowitz	72	Director

(1) Indicates independent director under NASDAQ rules.

(2) Member of our Audit Committee.

(3) Member of our Compensation Committee.

**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 thing, with establishing the national television of Tanzania and building the infrastructure of two cellular networks in Tanzania. Mr. Chirich serves as the

**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:EVGX) 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. Yaron Pereg** has served as our Chief Development Officer since January 1, 2017. From 2011 to 2016, Dr. Pereg served in various roles BioLineRx (NASDAQ:BLRX) with the most advanced one being its Senior Director of Oncology. Prior to his position with BioLineRx, from 2007 to 2010 Dr. Pereg held research and development positions in Genentech Inc., a biotechnology corporation and member of the Roche Group (ADR: RHHBY) and from 2010 to 2011 he held similar positions in the medical-device start-up company Glusense. Dr. Pereg has worked in the innovative biopharmaceutical industry for over a decade, leading worldwide non-clinical and clinical programs of multiple drug development projects managing multi-disciplinary teams and multi-million dollar budgets. He has a diverse experience in pharma and biotech R&D arena including preclinical, regulation, clinical, CMC and operational activities of drug development in the field of oncology.

**Dr. Amotz Nechushtan** has served as Vice President of Research and Development since May 2016. Prior to that, since July 2015 until May 2016, he served as Vice President of Product Development. Prior to joining the Company, Dr. Nechushtan served as Chief Executive Officer of Iluten Ltd from 2010 until 2013. Before that he served as Vice President of Research and Development of Target-in Ltd., Pharmaseed Ltd. and Quantomix Ltd. in the years 2001 to 2004. Dr. Nechushtan holds B.Sc., M.Sc. and Ph.D in biochemistry, all from the Hebrew University followed by 5 years post-doc at the NIH Bethesda, Maryland.

**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 Roitshtein Real Estate (TASE: ROTS), Orad Ltd., Allium Medical Ltd. (TASE: ALMD) and Nano Dimension Ltd. (TASE: NNDM). 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. She has over 22 years of experience in the biomedical field, including 14 years of management in the biotech industry, leading diverse corporate, business, operational, financial, clinical and regulatory development, and research activities. Since December 2014 Dr. Ben Yakar has served as Chief Executive Officer of BioSight Ltd., a private Israeli drug development company active in the field of oncology as a director on the board of directors at SHL Telemedicine (SHLTN: SW), and as a consultant to several biotech companies. From 2012 until 2014, Dr. Ben Yakar served as the Chief Executive Officer of Proconia (TASE: PRCG), a public biotech company traded on the TASE, and from 2012 until 2015 as a director at Israel Advanced Technology Industries. Prior to that, from 2011 until 2012, Dr. Ben Yakar was the Chief Executive Officer of Thrombotech, a biotechnology company established around thrombotic research at Hadassah Medical Center, where she led a multi-center clinical trial and led the company towards acquisition by D-Pharm Ltd. (TASE: DPRM). Prior to that, from 2009 until 2011, she served as the Chief Business Officer of YEDA Research and Development, the technology transfer company of the Weizmann Institute of Science, or WIS, responsible for the commercialization of the WIS technologies, and a Vice President in several biotech companies. Dr. Ben Yakar holds a PhD cum laude in molecular cell biology from the WIS. Her research, in the field of oncology, yielded several prestigious publications and awards.

**Yuval Berman** has served as a member of our board of directors since 2009. Mr. Berman serves as one of our external directors and serves on our audit committee, and compensation committee. Mr. Berman is the founder and managing director of U.V.B Business Initiatives Ltd., a business consultancy firm based in Tel Aviv established in 2002. Previously, Mr. Berman worked in the investment banking and underwriting units of Poalim Capital Markets & Investments Ltd. and Omega Investments Ltd., a publicly traded financial services group. Preceding this, Mr. Berman practiced corporate law for four years. Mr. Berman previously served on the board of directors of Elbit Vision Systems Ltd. (Nasdaq: EVSNF), as well as several private companies. He holds an LL.B. and B.A. degrees in Law and Economics from Tel Aviv University and an MBA from the Solvay Business School, Université Libre De Bruxelles. Mr. Berman is a member of the Israeli bar.

**David Grossman** has served as a member of our board of directors since November 2014. Mr. Grossman serves as one of our external directors and serves on our audit committee, and compensation committee. Since 2015, Mr. Grossman has served on the board of directors of Amnis Therapeutics Ltd. (TASE: AMNS) (formerly ITGI Medical Ltd.) and since 2014 he is the Chairman of Algomizer Ltd. (TASE: ALMO). Mr. Grossman previously served as Chief Executive Officer at XTL from 2009 until 2014, and was also a member of the board of directors from 2009 until 2013. He served on the audit committee of Green Fields Capital Ltd. from August 2011 to August 2014. He also served as a Vice President of Eurocom Investments LP, a private equity fund, from 2006 to 2009. Also during that time, Mr. Grossman served as Vice President of Sahar Investments Ltd. (TASE: ENLT; formerly SAIN), which focused on investments in the life sciences arena. Prior to that, Mr. Grossman was a Senior Analyst at Israel Health Care Ventures (IHCV), an Israeli healthcare venture capital fund. Mr. Grossman has previously served on a number of boards of public companies including Proteomics Ltd. (TASE: PRTL) and InterCure Ltd. (TASE: INCR) from 2012 to 2013, Rosetta Green Ltd. (TASE: RSTG) from 2011 to 2014, Bio Light Israeli Life Science Investments Ltd. (TASE: BOLT) from 2009 to 2011, and Gilat Satcom Ltd. (AIM: GLT) from 2007 to 2008. Mr. Grossman received a BA in Business Administration with a focus on information technology, from the Interdisciplinary Center Herzliya.

**Michael Berelowitz** has served as a member of our board of directors since March 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., a NASDAQ-listed clinical stage specialty pharmaceutical company, 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.

## 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.

## 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 directors and executive officers with respect to the year ended December 31, 2016 was \$1.65 million.

The table below sets forth the compensation paid to our five most highly compensated senior office holders (as defined in the Companies Law) during or with respect to the year ended December 31, 2016, 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 allowances)	Variable Compensation <sup>(1)</sup> (NIS in thousands)	Equity-Based Compensation <sup>(2)</sup> (NIS in thousands)	Other (NIS in thousands)	Total <sup>(3)</sup> (NIS in thousands)	Convenience translation into USD in thousands <sup>(6)</sup>
Dr. Shai Yarkoni, Chief Executive Officer & Director	1,598	350	243	5	2,196	571
Ronen Twito, Deputy Chief Executive Officer & Chief Financial Officer <sup>(4)</sup>	1,259	300	895	5	2,459	640
Moran Miron, Former Vice President Research and Development <sup>(5)</sup>	187	-	-	2	189	49
Kasbian Nuriel Chirich, Chairman of the Board of Directors	558	100	31	4	693	180
Dr. Amotz Nechushtan, Vice President Research and Development	466	-	101	1	568	148
Dr. Yaron Pereg, Chief Development Officer <sup>(7)</sup>	116	-	-	4	120	31

(1) Amounts reported in this column refer to variable compensation such as commission, incentive and bonus payments as recorded in our financial statements for the year ended December 31, 2016.

(2) Amounts reported in this column represent the expense recorded in our financial statements for the year ended December 31, 2016 with respect to equity-based compensation. Assumptions and key variables used in the calculation of such amounts are described in paragraph d of Note 14 to our audited consolidated financial statements, which are included in this prospectus.

(3) All amounts reported in the table are in terms of cost to our company, as recorded in our financial statements.

(4) Mr. Twito served as our prior Deputy Chief Executive Officer and Chief Financial Officer from November 2015 to January 1, 2017.

(5) On May 15, 2016, Ms. Miron ceased to serve as Vice President Research and Development.

(6) Calculated using the exchange rate reported by the Bank of Israel for December 31, 2016 at the rate of one U.S. dollar per NIS 3.845.

(7) Dr. Yaron Pereg employed in our company Since October 26, 2016 as Senior Director of Development and Operations and in January 26, 2017 appointed to Chief Development Officer.

On August 26, 2015, we granted options to purchase 72,000 ordinary shares to each of our directors, Mr. Chirich, Dr. Yarkoni, Mr. Nahmias, Dr. Ben Yakar, Mr. Berman and Mr. Grossman and to one former director. 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 December 7, 2015, we granted options to purchase 2,658,246 ordinary shares to Mr. Twito, our Deputy Chief Executive Officer and Chief Financial Officer. The options are exercisable at NIS 1.286 per share and expire on December 7, 2025. The options vest each quarter from the date of grant over three years in twelve equal installments.

On March 8, 2016, as part of a private placement, we granted 23,980 options to purchase 23,980 ordinary shares to Mr. Twito, our Deputy Chief Executive Officer and Chief Financial Officer, and 95,923 ordinary shares to Mr. Chirich, our chairman of the board of Directors, which was approved by the shareholders in June 2016. The options are exercisable at NIS 2.1 per share and expire on March 7, 2018.

On May 31, 2016, and On November 29, 2015 we granted 70,000 and 80,000 options respectively to purchase 70,000 and 80,000 ordinary shares to Dr. Amotz Nechushtan, our Vice President Research and Development. The options are exercisable at NIS 1.68 and 1.29 per share and expire on May 30, 2026 and on November 28, 2025 respectively

#### ***Employment Agreements with Executive Officers***

Our executive officers 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 executive officer, during which time the executive officer 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. 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. Under the agreement, Mr. Chirich is entitled to a salary of NIS 10,000 per month commencing July 1, 2013, and increasing in NIS 5,000 increments up to NIS 20,000 per month on each capital raise of over \$2 million. Mr. Chirich is gross salary in 2013 was NIS 20,000 per month. In addition, Mr. Chirich is entitled to a one-time bonus of 0.75% of the amount received in a capital raise if such amount raised is between \$1 million and \$2 million or 1% of the amount received in a capital raise if such amount raised is over \$2 million. As a result of our capital raise of NIS 15,000,000 in May 2014, Mr. Chirich was paid NIS 166,000 and as a result of our capital raise in 2015, Mr. Chirich became entitled to NIS 34,000. Mr. Chirich is entitled to an allocation to a manager’s insurance policy and study fund. Mr. Chirich is also entitled to reimbursement for reasonable out-of-pocket expenses, including travel expenses. The agreement has a term of 36 months and will be renewable for additional terms of 36 months subject to any approvals that are required by law. The agreement is terminable by either party upon 180 days prior written notice and is terminable immediately by Collect 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 for his service on the board of directors. 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 July 24, 2016, we entered into an extension and amendment to the employment agreement of our Chairman of the board of directors, Mr. Kasbian Nuriel Chirich, for an additional 36 month term. Our shareholders approved the Chirich Amendment at our shareholder meeting held on July 24, 2016. Pursuant to the terms of the Chirich Amendment, we will employ him on a part-time basis, consisting of at least 75% of his time, as the Chairman of the board of directors of the Company. Pursuant to the Chirich Amendment, Mr. Chirich will be entitled to a salary of NIS 30,000 per month and increasing to NIS 35,000 per month on a successful capital raise of over \$7.5 million in the aggregate. Mr. Chirich is currently being paid a gross salary of NIS 20,000 per month. Mr. Chirich is entitled to an allocation to a manager’s insurance policy and study fund. Mr. Chirich is also entitled to reimbursement for reasonable out-of-pocket expenses, including travel expenses. In addition, Mr. Chirich will be eligible to receive an annual bonus of up to NIS 100,000 for the year 2016, according to the objectives agreed by our compensation committee, our board of directors and subject to approval of a shareholder’s meeting, as follows: (1) if we raise between \$4 million and \$10 million in the aggregate, Mr. Chirich will be entitled to a bonus of NIS 50,000, (2) if we raise over \$10 million, Mr. Chirich will be entitled to a bonus of NIS 100,000, and (3) if we enter into a transaction (including a joint venture or other similar transaction) with a value of a minimum of \$2 million, Mr. Chirich will be entitled to a bonus of NIS 25,000, provided, however that in no event shall Mr. Chirich be entitled to a bonus in excess of NIS 100,000. In addition, Mr. Chirich will be entitled to an allocation to a manager’s insurance policy, pension plan, study fund and disability insurance. Mr. Chirich is also entitled to reimbursement for reasonable out-of-pocket expenses, including travel expenses. The agreement shall have a term of 36 months and will be renewable for additional terms of 36 months subject to any approvals that are required by law. The agreement is terminable by either party upon 180 days prior written notice and is terminable immediately by Collect for cause as such term is defined in the employment agreement.

#### ***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 of the Company. Under the agreement, commencing May 1, 2013, Dr. Yarkoni is entitled to a salary of NIS 45,000 per month, subject to cost of living increases. In addition, Dr. Yarkoni’s salary will increase by 10% on each capital raise of over \$2 million, up to a maximum increase of 20%. Dr. Yarkoni received monthly salary of NIS 54,450. In addition, under the agreement, upon the completion of the reverse merger that was completed on June 30, 2013, Dr. Yarkoni was entitled to a one-time bonus of NIS 100,000 which was paid to him during 2013. In addition, Dr. Yarkoni is entitled to a further one-time bonus of 0.75% of the amount received in a capital raise if such amount raised is between \$1 million and \$2 million or 1% of the amount received in a capital raise if such amount raised is over \$2 million. In December 2013, Dr. Yarkoni was paid a bonus of NIS 100,000 for the amounts raised during 2013 and as a result of our capital raise of NIS 15,000,000 in May 2014, Dr. Yarkoni was paid NIS 166,000 and as a result of our capital raise in 2015, Dr. Yarkoni became entitled to NIS 216,000. 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 has a term of 36 months and is terminable by either party upon 180 days prior written notice and terminable immediately by Collect Biotherapeutics 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 for his service on the board of directors. The options are exercisable at NIS 1.40 per share and expire on September 8, 2024. The options vest each quarter from the date of grant over three years in twelve equal installments.

On May 6, 2015, a special meeting of shareholders approved the payment of NIS 100,000 to Dr. Yarkoni for his activities in 2014. In addition, at the same meeting, our shareholders approved the targets for the payment of an annual bonus of up to five months’ salary for the year 2015 to Dr. Yarkoni. Based on his performance, Dr. Yarkoni was granted a bonus equal to four months’ salary during the 2015 fiscal year.

On August 26, 2015, we granted options to purchase 72,000 ordinary shares to Dr. Yarkoni for his service on the board of directors. 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 July 24, 2016, we entered into an extension and amendment to the employment agreement of our Chief Executive Officer, Dr. Shai Yarkoni or the Yarkoni Amendment. Our shareholders approved the Yarkoni Amendment at our shareholder meeting held on July 24, 2016. Pursuant to the terms of the Yarkoni Amendment, we intend to extend the term of his agreement for an additional 36 months, employing him on a full-time basis as our Chief Executive Officer. Pursuant to the Yarkoni Amendment, Dr. Yarkoni's monthly salary will be increased from NIS 54,450 to NIS 60,000, with a potential raise of such monthly salary to NIS 70,000 in the event of a successful capital raise of \$7.5 million. In addition, Dr. Yarkoni will be entitled to an allocation to a manager's insurance policy and study fund, as well as reimbursement for reasonable out-of-pocket expenses, including travel expenses and a company car and mobile phone. In addition, Dr. Yarkoni may be eligible for a bonus equal to up to five months' salary for the year 2016, according to the objectives agreed by our compensation committee, our board of directors, and subject to approval of a shareholder's meeting, including the following: (1) if we raise \$4 million or over and up to \$12 million in the aggregate, Dr. Yarkoni will be entitled to a bonus of two to four months' salary and if we raise more than \$12 million in the aggregate, Dr. Yarkoni will be entitled to a bonus of five months' salary, (2) if we successfully initiate our clinical trial, and after the recruitment of the sixth patient, Dr. Yarkoni will be entitled to a bonus of one month's salary, (3) if we successfully list our ADSs on Nasdaq, Dr. Yarkoni will be entitled to a bonus of one month's salary, (4) if we enter into a transaction (including a joint venture or other similar transaction) with a value of a minimum of \$2 million Dr. Yarkoni will be entitled to a bonus of two months' salary, and (5) upon the recommendation of the Board Dr. Yarkoni will be entitled to a bonus of one month's salary, provided, however, that in no event shall Dr. Yarkoni be entitled, in the aggregate, to a bonus in excess of five months' salary. The agreement has a term of 36 months and 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.

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### ***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.

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 vest on a quarterly basis in equal installments over 36 months and expire on September 28, 2025.

On August 26, 2015, we granted options to purchase 72,000 ordinary shares to Dr. Ben Yakar for her service on the board of directors. 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.

### ***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 of the Company. Under the agreement, commencing December 31, 2016, Mr. Leibovitz is entitled to a salary of NIS 52,500 per month. 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 180 days prior written notice and terminable immediately by Cellect Biotherapeutics 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 and expire on the earliest between December 31, 2016 or in case of termination of the employment with the company, option shall vest twelve months following the termination date. In addition, 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.

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### ***Employment Agreement with Dr. Yaron Pereg***

On September 8, 2016, we entered into an employment agreement with Dr. Yaron Pereg, employing him on full-time basis as Senior Director of Development and Operations, effective as of October 26, 2016. Under the agreement, Dr. Pereg is entitled to a salary of NIS 43,000 per month for the first 3 months of employment and NIS 45,000 per month for each month thereafter. In addition, Dr. Pereg will be entitled to an annual bonus equal up to 2 months' salary based upon the completion of certain targets to be determined by the Board of Directors. Dr. Pereg is entitled to an allocation to a manager's insurance policy and study fund. Dr. Pereg is also entitled to reimbursement for reasonable out-of-pocket expenses, including travel expenses, a company car and mobile phone. The agreement is terminable by either party upon 30 days prior written notice and terminable immediately by Cellect Biotherapeutics for cause as such term is defined in the employment agreement.

In addition, pursuant to the employment agreement, we granted to Dr. Pereg options to purchase 100,000 ordinary shares at an exercise price which will be determined according to the Board decision and according to the company options plan.

On January 1, 2017, the Company and Dr. Pereg amended the terms of his employment agreement, whereby Dr. Pereg was employed to serve as Chief Development Officer. In addition, Dr. Pereg's monthly salary was amended to NIS 45,000 per month and Dr. Pereg was granted options to purchase 250,000 ordinary shares at an exercise price of NIS 0.631 per share. The options vest on a quarterly basis in equal installments over 36 months and expire on the earliest between: (i) December 31st 2026; or, (ii) in case of termination of the employment with the Company, Options will be exercisable within a period of ninety days after the date of such termination.

## **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 and Kasbian Nuriel Chirich are independent under NASDAQ rules. The definition of independent director under

the NASDAQ rules and external directors 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 NASDAQ 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 eight directors, including at least two external directors required to be appointed under the Companies Law. Our board of directors currently consists of six members, including our non-executive Chairman of the board of directors.

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). See “Related Party Transactions” below. We are not a party to this founders 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 NASDAQ 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 Yuval Berman 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 2/3 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 Stock 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.

David Grossman and Yuval Berman have served as our external directors since 2014 and 2009 respectively, and both have the requisite accounting and financial expertise. David Grossman was elected to serve from November 9, 2014 to November 9, 2017. Yuval Berman was initially elected to serve from August 27, 2009 to August 27, 2012, reelected to serve an additional term from August 27, 2012 and until August 27, 2015 and reelected to serve a final term from August 27, 2015 until August 27, 2018. Our board of directors has determined that Yuval Berman has accounting and financial expertise.

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

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 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 NASDAQ, 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 three standing committees, the audit committee, the financial statement examination committee the compensation committee.

#### ***Audit Committee***

Our audit committee consists of Abraham Nahmias along with our two external directors, David Grossman and Yuval Berman. Mr. Berman 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 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 is 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 corporate governance rules. Our board of directors has determined that Yuval Berman and Abraham Nahmias are audit committee financial experts as defined by the SEC rules and have the requisite financial experience as defined by the NASDAQ 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 NASDAQ that sets forth the responsibilities of the audit committee consistent with the rules of the SEC and the listing rules of NASDAQ, as well as the requirements for such committee under the Companies Law, including the following:

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

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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”);
- where the board of directors approves the working plan of the internal auditor, to examine 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.

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#### ***Compensation Committee and Compensation Policy***

Our compensation committee consists of Abraham Nahmias along with our two external directors, David Grossman and Yuval Berman. Mr. Berman 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 NASDAQ, 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 needs to reference 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 the compensation policy at our annual general meeting of shareholders that was held in January 2014.

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) 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 to the 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 against 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

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- 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 of 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.

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#### **D. Employees.**

As of December 31, 2016, we had eighteen full-time employees. These employees are comprised of thirteen in research and development and five employees in management, finance and administration. From time to time, we also employ independent contractors to support our operations. Our employees are not represented

## 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, 2016, options to purchase 5,366,758 ordinary shares were outstanding and up to 2,796,242 ordinary shares are available for issuance. Of such outstanding options, options to purchase 2,905,925 ordinary shares were vested as of December 31, 2016, with a weighted average exercise price of NIS 1.47 per share, and will expire 10 years from the date of grant, during the years 2024 – 2026.

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.A below.

## ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### A. Major Shareholders

The following table presents as of March 20, 2017 (unless otherwise noted below), the beneficial ownership of our Ordinary Shares by each person who is known by us to be the beneficial owner of 5% or more of our outstanding Ordinary Shares (to whom we refer as our Major Shareholders), each of our directors; each of our named executive officers; and all directors and executive officers as a group. For purposes of Major Shareholders the data presented is based on information provided to us by the Major Shareholders or disclosed in public regulatory filings.

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 Ordinary Shares Beneficially Owned (1)	Percent of Class (2)
<b>Executive Officers and Directors</b>		
Nuriel Chirich Kasbian (3)	17,148,438	15.83%
Shai Yarkoni (4)	15,497,302	14.22%
Nadir Askenasy (5)	13,717,169	12.75%
Ronen Twito (6)	1,232,562	1.13%
Amotz Nechushtan (7)	57,500	*
Abraham Nahmias (8)	36,000	*
Ruth Ben Yakar (9)	119,333	*
Yaron Pereg (10)	41,667	*
Yuval Berman (11)	36,000	*
David Grossman (12)	36,000	*
Michael Berelowitz	-	-
<b>All directors and executive officers as a group (11 persons)</b>	<b>47,921,971</b>	<b>44.24%</b>
<b>Holders of more than 5% of our voting securities:</b>		

\* Less than 1%.

- (1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Ordinary Shares relating to options currently exercisable or exercisable within 60 days of the date of this table are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares shown as beneficially owned by them.
- (2) The percentages shown are based on 107,583,485 Ordinary Shares issued and outstanding as of March 20, 2017 plus Ordinary Shares relating to options currently exercisable or exercisable within 60 days of the date of this table, which are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person.
- (3) Includes (i) 16,425,615 ordinary shares owned by Mr. Chirich, (ii) options (Series 1) to purchase 342,500 ordinary shares at an exercise price of NIS 1.85 per share and expiring on June 30, 2016, (iii) options (Series A) to purchase 95,923 ordinary shares at an exercise price of NIS 2.1 per share and expiring on March 8, 2018, (iv) Warrants ADS to purchase 248,400 ordinary shares at an exercise price of NIS 1.95 (\$ 7.5) per share (per ADS) and expiring on July 29, 2021, (v) options to purchase 36,000 ordinary shares at an exercise price of NIS 1.90 per share and expiring on August 25, 2025. Excludes options to purchase 36,000 ordinary shares that vest in more than 60 days from March 20, 2017.
- (4) Includes (i) 14,095,762 ordinary shares owned by Mr. Yarkoni, (ii) options (Series 1) to purchase 70,000 ordinary shares at an exercise price of NIS 1.85 per share and expiring on June 30, 2016, (iii) Warrants ADS to purchase 295,540 ordinary shares at an exercise price of NIS 1.95 (\$ 7.5) per share (per ADS) and expiring on July 29, 2021, (iv) options to purchase 1,000,000 ordinary shares, at an exercise price of NIS 1.40 per share and expiring on September 8, 2024, and (v) options to purchase 36,000 ordinary shares at an exercise price of NIS 1.90 per share and expiring on August 26, 2025. Excludes options to purchase 236,000 ordinary shares that vest in more than 60 days from March 20, 2017.
- (5) Represents 13,717,169 ordinary shares owned by Dr. Askenasy.
- (6) Includes (i) 100,982 ordinary shares owned by Mr. Twito, (ii) options (Series A) to purchase 23,980 ordinary shares at an exercise price of NIS 2.1 per share and expiring on March 8, 2018, (iii) options to purchase 1,107,600 ordinary shares at an exercise price of NIS 1.286 per share and expiring on November 22, 2025.
- (7) Includes (i) options to purchase 40,000 ordinary shares at an exercise price of NIS 1.295 per share and expiring on November 28, 2025, (ii) options to purchase 17,500 ordinary shares at an exercise price of NIS 1.68 per share and expiring on May 30, 2026. Excludes options to purchase 92,500 ordinary shares that vest in more than 60 days from March 20, 2017.
- (8) Represents options to purchase 36,000 ordinary shares at an exercise price of NIS 1.90 per share and expiring on August 26, 2025. Excludes options to purchase 36,000 ordinary shares that vest in more than 60 days from March 20, 2017.
- (9) Represents (i) options to purchase 83,333 ordinary shares at an exercise price of NIS 1.40 per share and expiring on September 28, 2024, and (ii) options to purchase 36,000 ordinary shares at an exercise price of NIS 1.90 per share and expiring on August 26, 2025. Excludes options to purchase 52,667 ordinary shares that vest in more than 60 days from March 20, 2017.
- (10) Represents options to purchase 41,667 ordinary shares at an exercise price of NIS 0.631 per share and expiring on December 31, 2026. Excludes options to purchase 235,333 ordinary shares that vest in more than 60 days from March 20, 2017.
- (11) Represents options to purchase 36,000 ordinary shares at an exercise price of NIS 1.90 per share and expiring on August 26, 2025. Excludes options to purchase 36,000 ordinary shares that vest in more than 60 days from March 20, 2017.
- (12) Represents options to purchase 36,000 ordinary shares at an exercise price of NIS 1.90 per share and expiring on August 26, 2025. Excludes options to purchase 36,000 ordinary shares that vest in more than 60 days from March 20, 2017.
- (13) Includes (i) 16,906,455 ordinary shares owned by Michael Ilan Management and Investments Ltd., (ii) options (Series 1) to purchase 1,301,000 ordinary shares at an exercise price of NIS 1.85 per share and expiring on November 21, 2016, (iii) options (Series A) to purchase 143,884 ordinary shares at an exercise price of NIS 2.1 per share, (iv) Warrants ADS to purchase 576,930 ordinary shares at an exercise price of NIS 1.95 (\$ 7.5) per share (per ADS) and expiring on July 29, 2021.

### **Changes in Percentage Ownership by Major Shareholders**

#### **Record Holders**

Based upon a review of the information provided to us by our transfer agent and custodian bank in the United States, as of March 16, 2017, there were a total of seven holders of record of our shares, of which 1 record holder holding 19,529,960 shares, or approximately 17.7% of our outstanding shares had a registered address in the United States, five holders had registered addresses in Israel and one holder had a registered address in Panama. These numbers are not representative of the number of beneficial holders of our shares nor is it representative of where such beneficial holders reside, since many of these shares were held of record by brokers or other nominees.

The Company is not controlled by another corporation, by any foreign government or by any natural or legal persons except as set forth herein, and here are no arrangements known to the Company which would result in a change in control of the Company at a subsequent date. See "Related Party Transactions – Founders Agreement" for information regarding a voting agreement among certain of our shareholders.

#### **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**

On June 1, 2011, Kasbian Nuriel Chirich, our Chairman, Dr. Shai Yarkoni, our Chief Executive Officer and director, and Dr. Nadir Askenasy, our 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.

## Chirich Loans

In 2011, Kasbian Nuriel Chirich, our Chairman, lent to Collect Biotherapeutics, our subsidiary, \$140,000 bearing interest at 3% per annum and payable within 60 days upon written demand, but not earlier than April 2014. In May 2014, following our raise of NIS 15 million, we repaid the loan.

On December 11, 2012, Collect Biotherapeutics and Mr. Chirich entered into a loan agreement pursuant to which Collect Biotherapeutics borrowed \$50,000 from Mr. Chirich. The loan bore interest at Libor plus 3%. On April 30, 2013, Collect Biotherapeutics and Mr. Chirich entered into an amendment to the loan agreement pursuant to which the loan was converted into 697,324 ordinary shares of Collect Biotherapeutics.

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On February 7, 2013, Collect Biotherapeutics and Mr. Chirich entered into a loan agreement pursuant to which Collect Biotherapeutics borrowed NIS 100,000 from Mr. Chirich. The loan bore interest at Libor plus 3%. The loan was repaid during May 2013.

## Yarkoni Loans

On February 7, 2013, Collect Biotherapeutics and G.A.S.R. Biotechnology Ltd., or G.A.S.R., a company controlled by Dr. Shai Yarkoni, our Chief Executive Officer and director, entered into a loan agreement pursuant to which Collect Biotherapeutics borrowed NIS 100,000 from G.A.S.R. The loan bore interest at Libor plus 3%. The loan was repaid during May 2013.

## Michael Ilan

On May 13, 2014, Michael Ilan Management and Investments Ltd. (a private company wholly-owned by Mr. Michael Ilan), purchased 14,217,070 of our ordinary shares for NIS 15,000,000 in a private placement. As a result of this transaction, Michael Ilan became a related party.

## 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. 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. See "Board Practices — Exculpation, Insurance and Indemnification of Directors and Officers."

## Employment and Service Agreements

We have or have had employment, service or related agreements with each member of our senior management. See "Compensation" - "Employment Agreements with Executive Officers".

## 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.

On March 7, 2017, the Company petitioned the district court of Tel Aviv (the "Court") to approve the convening of a Special General Meeting of its shareholders for the purpose of (i) approving the extension of the expiration date of the Registrant's Series-1 Stock Options (the "Series-1 Stock Options") to a date that is 80 days from the Court's approval for such extension, if granted (the Court had previously extended the expiration date of the Series-1 Stock Options to June 30, 2017), (ii) to amend the exercise price of the Series-1 Stock Options from NIS 1.85 to NIS 1.20 and (iii) requesting shareholder approval for the proposed delisting of the Registrant's ordinary shares from the Tel Aviv Stock Exchange.

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In addition, the Company petitioned the Court to approve the convening of a Special General Meeting of the holders of its Series-1 Stock Options for the purpose of (i) approving the extension of the expiration date of the Series-1 Stock Options to a date that is 80 days from the Court's approval for such extension, if granted, and (ii) to amend the exercise price of the Series-1 Stock Options from NIS 1.85 to NIS 1.20

## 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 "Memorandum and Articles of Association — Dividends." See "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



**ITEM 9. THE OFFER AND LISTING**

**A. Offer and Listing Details**

Our Ordinary Shares have been trading on the TASE under the symbol “CLBD” since 1990. On July 29, 2016, our ADSs and warrants, commenced trading on the NASDAQ Capital Market under the symbols “APOP” and “APOPW”, respectively.

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our Ordinary Shares on the TASE in NIS and U.S. dollars. U.S. dollar per Ordinary Share amounts are calculated using the exchange rate reported by the Bank of Israel for December 31, 2016 at the rate of one U.S. dollar per NIS 3.845

	NIS Price Per Ordinary Share High	Low	U.S.\$ Price Per Ordinary Share High	Low
<b>Annual:</b>				
2017 (through March 20, 2017)	1.330	0.584	0.346	0.152
2016	1.998	0.45	0.519	0.120
2015	1.626	0.989	0.422	0.257
2014	1.531	0.705	0.398	0.183
2013	2.020	0.182	0.525	0.047
2012	1.706	0.169	0.443	0.043
<b>Quarterly:</b>				
First Quarter 2017 (through March 20, 2017)	1.330	0.584	0.346	0.152
Fourth Quarter 2016	0.844	0.45	0.219	0.120
Third Quarter 2016	1.593	0.825	0.414	0.214
Second Quarter 2016	1.998	1.338	0.519	0.347
First Quarter 2016	1.499	1.207	0.389	0.053
Fourth Quarter 2015	1.472	1.040	0.382	0.270
Third Quarter 2015	1.381	1.143	0.359	0.297
Second Quarter 2015	1.626	1.267	0.422	0.329
First Quarter 2015	1.501	0.989	0.390	0.257
<b>Most Recent Six Months:</b>				
March 2017 (through March 20, 2017)	1.276	1.108	0.332	0.288
February 2017	1.330	0.634	0.345	0.164
January 2017	0.871	0.584	0.226	0.151
December 2016	0.606	0.450	0.157	0.120
November 2016	0.815	0.612	0.211	0.159
October 2016	0.844	0.793	0.219	0.206
September 2016	0.916	0.825	0.238	0.214

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ADSs and warrants on the NASDAQ Capital Market in U.S. dollars.

	U.S.\$ Price Per ADS High	Low
<b>Annual:</b>		
2017 (through March 20, 2017)	6.850	3.068
2016 (from July 29, 2016)	5.300	2.660
<b>Quarterly:</b>		
First Quarter 2017 (through March 20, 2017)	6.850	3.068
Fourth Quarter 2016	4.630	2.660
Third Quarter 2016 (Since July 29, 2016)	5.300	4.390
<b>Most Recent Six Months:</b>		
March 2017 (through March 20, 2017)	6.850	6.230
February 2017	6.720	3.450
January 2017	6.110	3.068
December 2016	3.090	2.660
November 2016	4.150	3.200
October 2016	4.630	3.850
September 2016	4.760	4.400

**B. Plan of Distribution**

Not applicable.

**C. Markets**

Our Ordinary Shares are listed on the TASE. 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. Memorandum and Articles of Association**

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

***Purposes and Objects of the Company***

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

***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.

***Rights Attached to Shares***

Our Ordinary Shares shall confer upon the holders thereof:

- equal right to attend and to vote at all of our general meetings, whether regular or special, with each Ordinary Share entitling the holder thereof, which attend the meeting and participate at the voting, either in person or by a proxy or by a written ballot, to one vote;

- equal right to in distribution of dividends, if any, whether payable in cash or in bonus shares, in distribution of assets or in any other distribution, on a per share pro rata basis; and
- equal right to participate, upon our dissolution, in the distribution of our assets legally available for distribution, on a per share pro rata basis.

***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 and an issuance of shares for less than their nominal value, 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. 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;
- a merger;
- 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
- authorizing 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 authorize 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 and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

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;
- authorizing 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 authorize 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.

#### ***Changing Rights Attached to Shares***

Unless otherwise provided by the terms of the shares and subject to any applicable law, in order to change the rights attached to shares, such change must be adopted by the general meeting.

#### ***Limitations on the Right to Own Securities in Our Company***

There are no limitations on the right to own our securities.

## ***Provisions Restricting Change in Control of Our Company***

There are no specific provisions of our amended and restated articles of association that would have an effect of delaying, deferring or preventing a change in control of the Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving us (or our Subsidiary). However, as described below, certain provisions of the Companies Law may have such effect.

The Companies Law includes provisions that allow a merger transaction and requires that each company that is a party to the merger have the transaction approved by its board of directors and a vote of the majority of its shares. For purposes of the shareholder vote of each party, unless a court rules otherwise, the merger will not be deemed approved if shares representing a majority of the voting power present at the shareholders meeting and which are not held by the other party to the merger (or by any person who holds 25% or more of the voting power or the right to appoint 25% or more of the directors of the other party) vote against the merger. 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. In addition, a merger may not be completed unless at least (1) 50 days have passed from the time that the requisite proposals for approval of the merger were filed with the Israeli Registrar of Companies by each merging company and (2) 30 days have passed since the merger was approved by the shareholders of each merging company.

The Companies Law also provides that an acquisition of shares in a public company must be made by means of a "special" tender offer if as a result of the acquisition (1) the purchaser would become a 25% or greater shareholder of the company, unless there is already another 25% or greater shareholder of the company or (2) the purchaser would become a 45% or greater shareholder of the company, unless there is already a 45% or greater shareholder of the company. These requirements do not apply if, in general, the acquisition (1) was made in a private placement that received shareholder approval, (2) was from a 25% or greater shareholder of the company which resulted in the acquirer becoming a 25% or greater shareholder of the company, or (3) was from a 45% or greater shareholder of the company which resulted in the acquirer becoming a 45% or greater shareholder of the company. A "special" tender offer must be extended to all shareholders, but the offeror is not required to purchase more than 5% of the company's outstanding shares, regardless of how many shares are tendered by shareholders. In general, the tender offer may be consummated only if (1) at least 5% of the company's outstanding shares will be acquired by the offeror and (2) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer.

If, as a result of an acquisition of shares, the acquirer will hold more than 90% of a company's outstanding shares, the acquisition must be made by means of a tender offer for all of the outstanding shares. In general, if less than 5% of the outstanding shares are not tendered in the tender offer and more than half of the offerees who have no personal interest in the offer tendered their shares, all the shares that the acquirer offered to purchase will be transferred to it. Shareholders may request appraisal rights in connection with a full tender offer for a period of six months following the consummation of the tender offer, but the acquirer is entitled to stipulate that tendering shareholders will forfeit such appraisal rights.

Lastly, Israeli tax law treats some acquisitions, such as stock-for-stock exchanges between an Israeli company and a foreign company, less favorably than U.S. tax laws. For example, Israeli tax law may, under certain circumstances, subject a shareholder who exchanges his Ordinary Shares for shares in another corporation to taxation prior to the sale of the shares received in such stock-for-stock swap.

## ***Changes in Our Capital***

Pursuant to provisions of the Companies Law the general meeting may,

- increase our registered share capital by the creation of new shares from the existing class or a new class, as determined by the general meeting;
- cancel any registered share capital which have not been taken or agreed to be taken by any person;
- consolidate and divide all or any of our share capital into shares of larger nominal value than our existing shares;
- subdivide our existing shares or any of them, our share capital or any of it, into shares of smaller nominal value than is fixed;
- reduce our share capital and any fund reserved for capital redemption in any manner, and with and subject to any incident authorized, and consent required, by the Companies Law; and
- reduce shares from our issued and outstanding share capital, in such manner that those shares shall be cancelled and the nominal par value paid for those shares will be registered on our books as capital fund, which shall be deemed as a premium paid on those shares which shall remain in our issued and outstanding share capital.

## **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.A. History and Development of the Company" above, "Item 4.B. Business Overview" above, "Item 7A. Major Shareholders" or Item 7B. "Related Party Transactions" above.

## ***Underwriting Agreement***

On July 29, 2016, we entered into an underwriting agreement with H.C. Wainwright & Co., LLC, or Wainwright, as the representative of the underwriters named therein and book-running manager with respect to the public offering of our ADSs and warrants that were offered under a registration statement (Registration No. 333-212432). On August 3, 2016, we sold an aggregate of 1,292,308 ADSs and warrants to purchase 969,231 ADSs to the underwriters in the public offering. The net proceeds to the Company were approximately \$7.6 million (after deducting underwriters' fees).

## **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 resident companies, such as us, are generally subject to corporate tax at the rate of 25% as of January 1, 2016. In 2017 and 2018 the corporate tax rate will be 24% and 23% accordingly.

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

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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 over an eight-year period of the cost of purchased know-how and patents and rights to use a patent and know-how which are used for the development or advancement of the company; and
- under limited conditions, an election to file consolidated tax returns with related Israeli Industrial Companies.

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 amended 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 production facilities (or other eligible facilities), which are generally required to derive more than 25% of their business income from export 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).

From time to time, the Israeli Government has discussed reducing the benefits available to companies under the Investment Law. The termination or substantial reduction of any of the benefits available under the Investment Law could materially increase our tax liabilities.

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.

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### ***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, in any of the “means of control” of the corporation. “Means of control” generally include the right to vote, to 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; (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 (25% as of 2016 for corporations and up to 48% for individuals).

#### ***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, as amended, Israeli withholding tax on dividends paid to a U.S. resident for treaty purposes may not, in general, exceed 25%, or 15% in the case of dividends paid out of the profits of a “Approved Enterprise”, subject to certain conditions. 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.

#### ***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 AND AMERICAN DEPOSITORY SHARES, 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 sale 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 or the District of Columbia or any political subdivision thereof; (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. 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 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 aspects of U.S. federal income taxation that may be relevant to a particular U.S. Holder based on such holder's particular circumstances and in particular does not discuss any estate, gift, generation-skipping, transfer, state, local, excise or foreign tax considerations. In addition, this discussion does not address the U.S. federal income tax treatment of a U.S. Holder who is: (1) a bank, life insurance company, regulated investment company, or other financial institution or "financial services entity"; (2) a broker or dealer in securities or foreign currency; (3) a person who acquired our Ordinary Shares or ADSs or warrants in connection with employment or other performance of services; (4) a U.S. Holder that is subject to the U.S. alternative minimum tax; (5) a U.S. Holder that holds our Ordinary Shares 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) a tax-exempt entity; (7) real estate investment trusts; (8) a U.S. Holder that expatriates out of the United States or a former long-term resident of the United States; or (9) a U.S. Holder 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 or constructively, at any time, Ordinary Shares or ADSs or warrants representing 10% or more of our voting power. Additionally, the U.S. federal income tax treatment of persons who hold Ordinary Shares or ADSs or warrants through a partnership or other pass-through entity are not considered.

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 NASDAQ or another established securities market in the United States. Dividends will not qualify for the preferential rate if we are treated, in the year the dividend is paid or in the prior year, as a PFIC, as described 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***

Except as provided under the PFIC rules described below under "Passive Foreign Investment Companies," upon the sale, exchange or other disposition of our Ordinary Shares or ADSs or warrants, a U.S. Holder 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.

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.

Special U.S. federal income tax laws apply to U.S. taxpayers who own 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 that 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 (provided we were not considered a “controlled foreign corporation” prior to the public offering) 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.

Based on the nature of our business, the projected composition of our income and the projected composition and estimated fair market values of our assets, we may be classified as a PFIC. In addition, we may have been a PFIC in prior years and may be a PFIC in the future. U.S. Holders who hold Ordinary Shares 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 QEF or mark-to-market election.

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 who makes a QEF election for all taxable years that such U.S. Holder has held the Ordinary Shares or ADSs or warrants 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.

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. A U.S. Holder of our Ordinary Shares or ADSs or warrants which are regularly traded on a qualifying exchange, including Nasdaq, can elect to mark the Ordinary Shares or ADSs or warrants 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 or warrants 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 or warrants 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 or warrants would be treated as ordinary income, and any loss realized on the sale, exchange or other disposition of our Ordinary Shares or ADSs or warrants 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.

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 or warrants 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



### **Information Reporting and Withholding**

A U.S. Holder may be subject to backup withholding at a rate of 28% 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). You should consult your own tax advisor as to the possible obligation to file such information reports in light of your 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. You may read and copy the annual report on Form 20-F, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC will also be available to the public through the SEC's website at [www.sec.gov](http://www.sec.gov).

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.

In addition, since our Ordinary Shares are traded on the TASE, we have filed Hebrew language periodic and immediate reports with, and furnish information to, the TASE and the Israel Securities Authority, or the ISA, as required under Chapter Six of the Israel Securities Law, 1968. Copies of our filings with the ISA can be retrieved electronically through the MAGNA distribution site of the ISA ([www.magna.isa.gov.il](http://www.magna.isa.gov.il)) and the TASE website ([www.maya.tase.co.il](http://www.maya.tase.co.il)).

We maintain a corporate website [www.collectbio.com](http://www.collectbio.com). 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.

#### **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.

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### 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)

**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

\$.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

Depository services

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

Registration or transfer fees

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

Expenses of the depositary

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

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

As necessary

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

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 depository 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.

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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.

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## PART II

### ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

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

## **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 American Depository Shares (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 Powered by Collect technology platform for additional indications and for general research activities as well as for working capital and other general corporate purposes.

As of March 20, 2017, we have used approximately \$2.2 million of the net proceeds of this offering for on going R&D and clinical research, approximately \$1.1 million to working capital; and any other purposes.

We expect to use the additional net proceeds from this offering as follows:

Approximately \$2.9 million to on going R&D and clinical research, and approximately \$1.4 million to working capital; and any other purposes.

We believe that the net proceeds from the offering, together with our cash reserves preceding the offering, should be sufficient to complete Our clinical activates as planned.

Our expected use of net proceeds from the offering represents our current intentions based upon our present plans and business condition. As of the date of this annual report, we cannot predict with certainty any or all of the particular uses for the net proceeds we received upon the completion of the offering, or the amounts, if any, that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors. As a result, our management will have broad discretion in the application of the net proceeds, which may include uses not set forth above, and investors in our securities will be relying on our judgment regarding the application of the net proceeds from the offering.

## **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, 2016, 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**

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

### **(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, 2016, 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: Yuval Berman 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 Nasdaq 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 NASDAQ 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.collectbio.com](http://www.collectbio.com). 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, 2016 and 2015.

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, 2016 and 2015:

	Year Ended December 31,	
	2015	2016
(in thousands)		
Audit fees <sup>(1)</sup>	\$ 32	61
Audit-related fees	50	146
Tax fees <sup>(2)</sup>	4	19
All other fees	-	20
Total	<u>\$ 86</u>	<u>246</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, transfer pricing and consulting on state and sales tax in the United States.

#### **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 Stock 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 Stock Market rules for U.S. domestic issuers.

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

*Distribution of certain reports to shareholders.* As opposed to the listing rules of 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 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 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 NASDAQ. See "— Compensation Committee and

*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 NASDAQ 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 NASDAQ 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 NASDAQ 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: David Grossman, Yuval Berman and Abraham Nahmias qualifies as “independent” under NASDAQ 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 NASDAQ Listing Rule 5635. In particular, under this NASDAQ 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 NASDAQ. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other NASDAQ corporate governance rules. Following our home country 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.

#### 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	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).
1.2	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 as filed with the Securities and Exchange Commission on July 25, 2016, and incorporated herein by reference).
2.1	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 as filed with the Securities and Exchange Commission on July 26, 2016, and incorporated herein by reference).
2.2	Specimen American Depositary Receipt (included in Exhibit 2.1)
2.3	Form of Warrant Agent Agreement (included as Exhibit 4.3 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on July 26, 2016, and incorporated herein by reference).
2.4	Form of Underwriters' Warrant (included as Exhibit 4.4 to our Registration Statement on Form F-1 as filed with the Securities and Exchange Commission on July 26, 2016, and incorporated herein by reference).
4.1	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).
4.2	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).

- 4.3 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).
- 4.4 Employment Agreement dated October 14, 2015 between Collect Biotechnology Ltd. and Ronen Twito (included as Exhibit 10.4 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).
- 4.5 Consulting Agreement dated April 30, 2013 between Collect Biotechnology Ltd. and Dr. Nadir Askenasy (unofficial English translation from Hebrew original) (included as Exhibit 10.5 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).

- 4.6 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).
- 4.7 Joint Product Development Agreement dated June 17, 2015 between Collect Biotechnology Ltd. and Entegris Inc (included as Exhibit 10.7 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).
- 4.8 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).
- 8.1 Subsidiaries of Collect Biotechnology Ltd. (included as Exhibit 21.1 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).
- 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.

**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 23, 2017

**CELLECT BIOTECHNOLOGY LTD  
(FORMERLY CELLECT BIOMED LTD.)**

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF DECEMBER 31, 2016**

**NIS IN THOUSANDS**

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and  
Board of Directors of

Collect Biotechnology Ltd.

We have audited the accompanying consolidated balance sheets of Collect Biotechnology Ltd. (the "Company") and its subsidiaries as of December 31, 2016 and 2015 and 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, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries at December 31, 2016 and 2015 and the consolidated results of their operations, changes in equity and cash flows for each of the three years in the period ended December 31, 2016, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Without qualifying our above opinion, we draw attention to Note 1b to the consolidated financial statements. As discussed in Note 1b to the financial statements, the Company incurred negative cash flow from operations totaling NIS 14,412 and losses totaling NIS 15,317 thousand during the year ended December 31, 2016, has not yet generated revenues from its operations and is dependent on external sources for financing its operations. These factors, among others discussed in Note 1b, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are discussed in Note 1b. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Tel-Aviv, Israel  
March 22, 2017

KOST FORER GABBAY & KASIERER  
A Member of Ernst & Young Global

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CELLECT BIOTECHNOLOGY LTD.

CONSOLIDATED BALANCE SHEETS

In thousands, except number of shares data

	Note	December 31,		Convenience translation (Note 2d)
		2015	2016	December 31, 2016
		NIS		U.S. dollars
<b>CURRENT ASSETS:</b>				
Cash and cash equivalents	6	3,913	6,279	1,633
Sort term deposits	7	-	19,660	5,113
Marketable securities	8	7,829	4,997	1,300
Other receivables	9	412	1,461	380
		12,154	32,397	8,426
<b>LONG-TERM ASSETS:</b>				
Restricted cash		20	140	36
Property, plant and equipment, net	10	1,187	1,373	357
		1,207	1,513	393
		13,361	33,910	8,819
<b>CURRENT LIABILITIES:</b>				
Trade payables	11	466	1,401	364
Other payables	12	2,394	2,084	542
		2,860	3,485	906
<b>NON CURRENT LIABILITIES:</b>				
Traded warrants to ADS		-	1,938	504
<b>SHAREHOLDERS' EQUITY :</b>				
Ordinary shares of no par value:	13	-	-	-
Authorized: 500,000,000 shares at December 31, 2015, and 2016, Issued and outstanding: 75,949,888*) and 107,583,485*) shares as of December 31, 2015 and 2016, respectively.				
Additional Paid In Capital		36,725	67,414	17,533
Share-based payments	14	3,603	6,217	1,617
Treasury shares		(9,425)	(9,425)	(2,451)
Accumulated deficit		(20,402)	(35,719)	(9,290)

10,501 28,487 7,409

13,361 33,910 8,819

\*) Net of 2,686,693 treasury shares of the Company, held by the Company.

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

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CELLECT BIOTECHNOLOGY LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands, except number of shares data

	Note	Year ended December 31,			Convenience translation (Note 2d)
		2014	2015	2016	Year ended December 31, 2016
		NIS			U.S. dollars
Research and development expenses	17a	3,058	5,893	8,256	2,147
General and administrative expenses	17b	2,491	4,204	7,968	2,072
Other Income		-	-	(280)	(73)
Total operating expenses		5,549	10,097	15,944	4,146
Operating loss		5,549	10,097	15,944	4,146
Financial income		(37)	(4)	(660)	(172)
Financial expenses		39	79	33	9
Total Comprehensive loss		5,551	10,172	15,317	3,983

Loss per share

Basic and diluted loss per share	18	0.084	0.137	0.168	0.044
Weighted average number of shares outstanding used to compute basic and diluted loss per share		65,968,768	74,475,109	91,128,516	91,128,516

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

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CELLECT BIOTECHNOLOGY LTD.

STATEMENTS OF CHANGES IN EQUITY

In thousands, except number of shares data

	Share capital	Share premium	Treasury shares	Share based payments	Accumulated deficit	Total equity
	NIS					
Balance as of January 1, 2014	-	16,764	(9,425)	583	(4,679)	3,243
Issuance of share capital net of issue costs (see Note 13a1)	-	14,140	-	329	-	14,469
Share-based payment	-	-	-	798	-	798
Total comprehensive loss	-	-	-	-	(5,551)	(5,551)
Balance as of December 31, 2014	-	30,904	(9,425)	1,710	(10,230)	12,959
Issuance of share capital net of issue costs (see Note 13a2)	-	5,596	-	696	-	6,292
Share-based payment	-	-	-	1,318	-	1,318
Exercise of share options	-	225	-	(121)	-	104
Total comprehensive loss	-	-	-	-	(10,172)	(10,172)
Balance as of December 31, 2015	-	36,725	(9,425)	3,603	(20,402)	10,501
Issuance of share capital net of issue costs (see Note 13a4, 5)	-	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)
Balance as of December 31, 2016	-	67,414	(9,425)	6,217	(35,719)	28,487
Balance as of December 31, 2016 convenience translation in U.S. dollars (see Note 2d)	-	17,533	(2,451)	1,617	(9,290)	7,409

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

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CELLECT BIOTECHNOLOGY LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands, except number of shares data

	Year ended December 31,			Convenience translation (Note 2d)
	2014	2015	2016	Year ended December 31, 2016
	NIS			U.S. dollars
<b>Cash Flows from Operating Activities:</b>				
Total Comprehensive Loss	(5,551)	(10,172)	(15,317)	(3,983)
Adjustments to reconcile net loss to net cash used in operating activities:				
Adjustments to profit and loss items:				
Net financing expenses	3	69	134	35
Gain from revaluation of financial assets presented at fair value through profit and loss	(35)	(2)	(106)	(28)
Depreciation and capital loss from sale of property, plant and equipment	24	71	350	91
Interest and indexation differences in respect of loans from shareholder, net	21	-	-	-
Share-based payment	798	1,318	1,552	404
Changes in fair value of traded warrants to ADS	-	-	(1,235)	(321)
	811	1,456	695	181
Changes in asset and liability items:				
Decrease (increase) in other receivables	104	(328)	(1,049)	(273)
Increase in other payables	235	1,333	1,259	327
	339	1,005	210	54
Cash paid and received during the year for:				
Interest received	2	1	-	-
	2	1	-	-
Net cash used in operating activities	(4,399)	(7,710)	(14,412)	(3,748)
<b>Cash Flows from Investing Activities:</b>				
Proceeds received from the sale of fixed assets	-	77	95	25
Short term deposits	-	-	(19,530)	(5,079)
Restricted deposit	-	-	(120)	(31)
Investment in marketable securities measured at fair value through profit and loss	(14,022)	-	-	-
Sales of Marketable securities measured at fair value through profit and loss	2,800	3,430	2,808	730
Purchase of property, plant and equipment	(229)	(332)	(1,265)	(329)
Net cash provided by (used in) investing activities	(11,451)	3,175	(18,012)	(4,684)

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

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CELLECT BIOTECHNOLOGY LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands, except number of shares data

	Year ended December 31,			Convenience translation (Note 2d)
	2014	2015	2016	Year ended December 31, 2016
	NIS			U.S. dollars

<b>Cash Flows from Financing Activities:</b>				
Exercise of share options	-	104	7	2
Repayment of loans from shareholders	(536)	-	-	-
Issuance of share capital, net of issue costs (see note 13)	14,469	6,292	34,917	9,081
<b>Net cash provided by financing activities</b>	<b>13,933</b>	<b>6,396</b>	<b>34,924</b>	<b>9,083</b>
<b>Exchange differences on balances of cash and cash equivalents</b>	<b>(5)</b>	<b>(70)</b>	<b>(134)</b>	<b>(35)</b>
<b>Increase (decrease) in cash and cash equivalents</b>	<b>(1,922)</b>	<b>1,791</b>	<b>2,366</b>	<b>616</b>
<b>Balance of cash and cash equivalents at the beginning of the year</b>	<b>4,044</b>	<b>2,122</b>	<b>3,913</b>	<b>1,018</b>
<b>Balance of cash and cash equivalents at the end of the year</b>	<b>2,122</b>	<b>3,913</b>	<b>6,279</b>	<b>1,634</b>
<b>(a) Non-cash activities:</b>				
Purchase of property, plant and equipment	-	692	58	15

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

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**CELLECT BIOTECHNOLOGY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In thousands, except number of shares data

**NOTE 1:- GENERAL**

- a. Collect Biotechnology Ltd. (formerly Collect Biomed Ltd.) (the "Company" or "Collect") is a public company whose shares are listed for trading on the Tel Aviv Stock Exchange (the "TASE") and whose American Depository Shares ("ADSs"), each representing twenty of the Company's ordinary shares, and traded warrants to ADS are listed for trading on the NASDAQ (see also note B.5). Collect and its subsidiary, Collect Biotherapeutics Ltd. (the "Subsidiary") are engaged in the development of an innovative, unique technology that enables the biological filtering and commercialization of stem cells.

- 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, 2016, the Company incurred a net loss of NIS 15,317 (\$3,983) and had negative cash flows from operating activities of NIS 14,412 (\$3,748). In addition, the Company had an accumulated deficit of NIS 35,719 (\$9,290) at December 31, 2016. 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 2018.

The Company's activities since inception have consisted of raising capital and performing research and development activities. As of December 31, 2016, 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, 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. 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.

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**CELLECT BIOTECHNOLOGY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In thousands, except number of shares data

**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 IFRS as issued by the International Accounting Standards Board ("IASB").

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 the Company controls (subsidiaries). Control exists when the Company has the power, directly or indirectly, to govern the financial and operating policies of an entity. 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 intercompany transactions are eliminated in full in the consolidated financial statements.

c. Functional currency, reporting currency and foreign currency:

1. Functional currency and reporting currency:

The reporting currency of the financial statements is the New Israeli Shekel ("NIS").

The Company determines the functional currency of each company in the Group, 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, 2016 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, 2016 (U.S. \$1.00 = NIS 3.845). 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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In thousands, except number of shares data**

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

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 acquisition.

f. Taxes on income:

Tax results with respect to current or deferred taxes are recognized in profit or loss, unless they relate to items recognized in other comprehensive income or equity.

*Current taxes*

The liability for current taxes is determined using the tax rates and tax laws that were enacted, or essentially enacted, by the reporting date, as well as adjustments required in connection with the taxes payable in respect of prior years.

g. 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
Vehicles	20
Leasehold improvements	(*)
Office furniture and equipment	7 - 15

(\*) Leasehold improvements are depreciated on a straight-line basis over the lease term or the estimated useful life of the improvement, according to the shorter period.

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. An asset is derecognized upon disposal or when no further economic benefits are expected from its use.

During 2016, the Company sold its sole vehicle and as of December 31, 2016 the Company doesn't own any vehicles in its possession.

h. 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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****In thousands, except number of shares data****NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

## i. Financial instruments:

## 1. Financial assets:

Financial assets within the scope of International Accounting Standard (IAS) 39, "*Financial Instruments: Recognition and Measurement*" ("IAS 39") are initially recognized at fair value plus directly attributable transaction costs, except for financial assets measured at fair value through profit or loss in respect of which transaction costs are recorded in profit or loss.

After initial recognition, the accounting treatment of financial assets is based on their classification as follows:

Financial assets at fair value through profit or loss

This category includes financial assets designated upon initial recognition at fair value through profit or loss.

Loans and receivables

Loans and receivables are investments with fixed or determinable payments that are not quoted in an active market. After initial recognition, loans are measured based on their terms at amortized cost plus directly attributable transaction costs using the effective interest method and less any impairment losses. Short-term borrowings are measured based on their terms, normally at face value.

## 2. Financial liabilities:

Financial liabilities within the scope of IAS 39 are initially measured at fair value.

After initial recognition, the accounting treatment of financial liabilities is based on their classification as follows:

Financial liabilities measured at amortized cost:

After initial recognition, loans and other liabilities are measured according to their terms at amortized cost using the effective interest method, taking into account directly attributable transaction costs.

## 3. Offsetting financial instruments:

Financial assets and financial liabilities are offset and the net amount is presented in the statement of financial position if there is a legally enforceable right to set off the recognized amounts and there is an intention either to settle on a net basis or to realize the asset and settle the liability simultaneously.

## j. Onerous contract

The Company recognized a net provision for contractual future lease payment amounts greater than the future economic benefits expected from leased assets (expected income from sublease of the assets) as a result of discontinuing use of the assets, departure and transfer of activities carried out in them. This provision is presented at present value.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****In thousands, except number of shares data****NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

## k. 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.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

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).

l. 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.

m. Employee benefit liabilities:

The Group has several employee benefit plans:

1. Short-term employment benefits:

Short-term employee benefits are expected to be settled in full less than 12 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. The liability for a cash bonus or profit-participating plan is recognized when the Company has a legal or constructive obligation to pay the said amount in respect of past services rendered by the employee and the amount may be reliably estimated.

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CELLECT BIOTECHNOLOGY LTD.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In thousands, except number of shares data**

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

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.

n. Share-based payment transactions:

From time to time the Company grants to its employees and other service providers remuneration in the form of equity-settled share-based instruments, such as options to purchase ordinary shares.

*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. 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 (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.

When the Company changes 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.

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CELLECT BIOTECHNOLOGY LTD.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In thousands, except number of shares data**

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (cont.)**

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.

o. 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.

**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**

a. IFRS 15, "Revenue from Contracts with Customers":

IFRS 15 ("the new Standard") was issued by the IASB in May 2014.

The new Standard replaces IAS 18, "Revenue", IAS 11, "Construction Contracts", IFRIC 13, "Customer Loyalty Programs", IFRIC 15, "Agreements for the Construction of Real Estate", IFRIC 18, "Transfers of Assets from Customers" and SIC-31, "Revenue - Barter Transactions Involving Advertising Services".

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CELLECT BIOTECHNOLOGY LTD.

**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.)**

The new Standard introduces a five-step model that will apply to revenue earned from contracts with customers:

Step 1: *Identify the contract with a customer*, including reference to contract combination and accounting for contract modifications.

Step 2: *Identify the separate performance obligations in the contract*

Step 3: *Determine the transaction price*, including reference to variable consideration, financing components that are significant to the contract, non-cash consideration and any consideration payable to the customer.

Step 4: *Allocate the transaction price to the separate performance obligations* on a relative stand-alone selling price basis using observable information, if it is available, or using estimates and assessments.

Step 5: *Recognize revenue when a performance obligation is satisfied*, either at a point in time or over time.

The new Standard is to be applied for annual periods beginning on January 1, 2018. Early adoption is permitted. At this stage, the Company does not intend to adopt IFRS 15 early.

The new Standard allows the option of modified retrospective adoption with certain reliefs according to which the new Standard will be applied to existing contracts from the initial period of adoption and thereafter with no restatement of comparative data. Under this option, the Company will recognize the cumulative effect of the initial adoption of the new Standard as an adjustment to the opening balance of retained earnings (or another component of equity, as applicable) as of the date of initial application. Alternatively, the new Standard permits full retrospective adoption with certain reliefs.

b. IFRS 9, "Financial Instruments":

In July 2014, the IASB issued the final and complete version of IFRS 9, "Financial Instruments" ("IFRS 9"), which replaces IAS 39, "Financial Instruments: Recognition and Measurement". IFRS 9 mainly focuses on the classification and measurement of financial assets and it applies to all assets in the scope of IAS 39.

According to IFRS 9, all financial assets are measured at fair value upon initial recognition. In subsequent periods, debt instruments are measured at amortized cost only if both of the following conditions are met:

- The asset is held within a business model whose objective is to hold assets in order to collect the contractual cash flows.

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CELLECT BIOTECHNOLOGY LTD.

**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.)**

- the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

IFRS 9 also includes a new model for measurement of impairment of financial assets.

Subsequent measurement of all other debt instruments and financial assets should be at fair value. IFRS 9 establishes a distinction between debt instruments to be measured at fair value through profit or loss and debt instruments to be measured at fair value through other comprehensive income.

Financial assets that are equity instruments should be measured in subsequent periods at fair value and the changes recognized in profit or loss or in other comprehensive income (loss), in accordance with the election by the Company on an instrument-by-instrument basis. If equity instruments are held for trading, they should be measured at fair value through profit or loss.

According to IFRS 9, the provisions of IAS 39 will continue to apply to derecognition and to financial liabilities for which the fair value option has not been elected.

According to IFRS 9, changes in the fair value of financial liabilities which are attributable to the change in credit risk should be presented in other comprehensive income. All other changes in fair value should be presented in profit or loss.

IFRS 9 also prescribes new hedge accounting requirements.

IFRS 9 is to be applied for annual periods beginning on January 1, 2018. Early adoption is permitted.

The Company is evaluating the possible impact of the adoption of IFRS 9 but is presently unable to assess its effect, if any, on the financial statements.

c. Amendments to IAS 7, "Statement of Cash Flows", regarding additional disclosures of financial liabilities:

In January 2016, the IASB issued amendments to IAS 7, "Statement of Cash Flows", (the "Amendments") which require additional disclosures regarding financial liabilities. The Amendments require disclosure of the changes between the opening balance and the closing balance of financial liabilities, including changes from cash flows, changes arising from obtaining or losing control of subsidiaries, the effect of changes in foreign exchange rates and changes in fair value.

The Amendments are effective for annual periods beginning on or after January 1, 2017. Comparative information for periods prior to the effective date of the Amendments is not required. Early application is permitted.

The Company will include the necessary disclosures in the financial statements when applicable.

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CELLECT BIOTECHNOLOGY LTD.

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**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.)**

d. 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.

According to the New Standard:

- 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.
- The new Standard 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.

The New Standard is effective for annual periods beginning on or after January 1, 2019. Earlier application is permitted provided that IFRS 15, "Revenue from Contracts with Customers", is applied concurrently.

For leases existing at the date of transition, the New Standard 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.

The Company is evaluating the possible impact of the adoption of IFRS 16 but is presently unable to assess its effect, if any, on the financial statements.

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CELLECT BIOTECHNOLOGY LTD.

**NOTE 5:- MERGER WITH CELLECT BIOTHERAPEUTICS LTD. (formerly "Collect Biotechnology Ltd")**

The merger between the Company and the Subsidiary, a private company engaged in development of innovative, unique technology, enabling selection of biologically filtered stem cells and commercialization, closed on July 1, 2013. Under the terms of the agreement, 44,887,373 ordinary shares, NIS 1.00 par value each, of the Company, constituting 85% of its equity, were issued to shareholders of the Subsidiary, as well as an aggregate of 568,395 options (not listed for trading), each exercisable for one ordinary share of the Company, NIS 1.00 par value each, in consideration for the entire share capital of the Subsidiary including all of the existing options in the Subsidiary, such that following the merger, the Subsidiary became a wholly-owned subsidiary of the Company.

Out of the options granted, an amount of 227,358 Series 1 unlisted options – exercisable until April 30, 2018, at an exercise price of NIS 1.00 per option.

**NOTE 6:- CASH AND CASH EQUIVALENTS**

	December 31,		Convenience translation (Note 2d)
	2015	2016	December 31, 2016
	N I S		U.S. dollars
Cash for immediate withdrawal	3,913	6,279	1,633
	<u>3,913</u>	<u>6,279</u>	<u>1,633</u>

**NOTE 7: SHORT TERM DEPOSITS**

	December 31,		Convenience translation (Note 2d)
	2015	2016	December 31, 2016
	N I S		U.S. dollars
Short Term Deposits	-	19,660	5,113
	<u>-</u>	<u>19,660</u>	<u>5,113</u>

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In thousands, except number of shares data

**NOTE 8:- MARKETABLE SECURITIES MEASURED AT FAIR VALUE THROUGH PROFIT AND LOSS**

Marketable securities measured at fair value through profit and loss. As of December 31, 2016, the marketable securities are comprised of NIS mutual funds that follow changes in short term Bank of Israel interest.

**NOTE 9:- OTHER RECEIVABLES**

	December 31,		Convenience translation (Note 2d)
	2015	2016	December 31, 2016
	N I S		U.S. dollars
Other receivables	-	51	13
Government authorities	187	611	159
Prepaid expenses	225	799	208
	<u>412</u>	<u>1,461</u>	<u>380</u>

**NOTE 10:- PROPERTY, PLANT AND EQUIPMENT, NET**

Balance as of December 31, 2016:

<i>Cost</i>	Laboratory	Leasehold	Vehicles	Office	Computers	Total
	equipment	improvements		furniture and equipment		
Balance as of January 1, 2016	687	244	176	36	149	1,292
Additions during the year	319	128	-	111	83	641
Deductions during the year	-	-	(176)	-	-	(176)
Balance as of December 31, 2016	<u>1006</u>	<u>372</u>	<u>-</u>	<u>147</u>	<u>232</u>	<u>1,757</u>
<i>Accumulated Depreciation</i>						
Balance as of January 1, 2016	12	-	37	8	48	105
Additions during the year:	128	116	25	10	62	341
Deductions during the year	-	-	(62)	-	-	(62)



Balance as of December 31, 2016	140	116	-	18	110	384
Depreciated cost as of December 31, 2016	866	256	-	129	122	1,373
Depreciated cost as of December 31, 2016 (convenience translation into U.S. dollars (Note 2d))	225	67	-	34	32	357

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CELLECT BIOTECHNOLOGY LTD.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In thousands, except number of shares data

**NOTE 10:- PROPERTY, PLANT AND EQUIPMENT, NET (Cont.)**

Balance as of December 31, 2015:

	Laboratory equipment	Leasehold improvements*)	Vehicles	Office furniture and equipment	Computers	Total
<b>Cost</b>						
Balance as of January 1, 2015	-	-	176	16	76	268
Additions during the year:	687	244	-	20	73	1,024
Balance as of December 31, 2015	687	244	176	36	149	1,292
<b>Accumulated Depreciation</b>						
Balance as of January 1, 2015	-	-	11	6	17	34
Additions during the year:						
Depreciation	12	*)-	26	2	31	71
Balance as of December 31, 2015	12	-	37	8	48	105
Depreciated cost as of December 31, 2015	675	244	139	28	101	1,187

\*) The Company entered into new offices in early January 2016, and did not record depreciation expenses of the leasehold improvements during 2015.

**NOTE 11:- TRADE PAYABLES**

	December 31,		Convenience translation (Note 2d)
	2015	2016	December 31,
	N I S		2016
			U.S. dollars
Service providers	182	1,343	349
Notes payable	284	58	15
	466	1,401	364

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CELLECT BIOTECHNOLOGY LTD.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In thousands, except number of shares data

**NOTE 12:- OTHER PAYABLES**

	December 31,		Convenience translation (Note 2d)
	2015	2016	December 31,
	N I S		2016
			U.S. dollars
Employees and payroll accruals *)	663	1,677	436
Accrued expenses	985	393	102
Payables for acquisition of property, plant and equipment	692	-	-
Other	54	14	4
	2,394	2,084	542

\*) Balance includes related parties (The Company's CEO and the Chairman of the Board of Directors).

## a. Changes in share capital:

	<b>Number of Shares</b>
<u>Balance as of January 1, 2015</u>	71,085,351
Exercise of share options – see note 8 below	341,037
Issuance of shares – see note 7 below	4,523,500
<u>Balance as of December 31, 2015</u>	*)75,949,888
Issuance of shares in private placement	5,783,437
Exercise of share options	4,000
Issuance of shares in an IPO	25,846,160
<u>Balance as of December 31, 2016</u>	<u>*)107,583,485</u>

\*) Net of 2,686,693 treasury shares of the Company, held by the Company.

- On April 22, 2014, the Company's board of directors approved the Company entering into an investment agreement (the "Private Placement") with Michael Ilan Management and Investments Ltd., a private company wholly-owned by Mr. Michael Ilan (the "Investor"), whereby the Investor agreed to invest the sum of NIS 15,000 according to a pre-money company valuation of NIS 60,000, for consideration of 14,217,070 ordinary shares of the Company, representing, after issuance, 20% of the Company's issued and outstanding capital and 19.84% on a fully-diluted basis. On May 13, 2014 the Private Placement was completed.

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**CELLECT BIOTECHNOLOGY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In thousands, except number of shares data**

**NOTE 13:- EQUITY (Cont.)**

Additionally, the Company entered into an agreement with a broker (the "Broker"), pursuant to which the Company agreed that at the closing of the Private Placement, the Broker would be entitled to cash compensation of 3% of the amount of the investment (NIS 450), plus options that are exercisable over three years from their grant date, in an amount equal to 3% of the share capital to be issued to investor. Following closing, a total of 426,512 options, exercisable into 426,512 ordinary shares, were granted to the Broker. The total benefit in respect of the grant calculated at the grant date was NIS 329.

- On April 20, 2015, the Company published an offering under the shelf registration statement and prospectus dated November 25, 2014, pursuant to which the public was offered up to 4,500,000 shares and up to 4,500,000 options (Series 1), exercisable into 4,500,000 ordinary shares of the Company. The Company exercised its right for an over-allotment not to exceed 15% of the total securities offered through the offering, such that in total, the Company issued 4,523,500 ordinary shares and 4,523,500 options (Series 1) of the Company. The total gross proceeds received by the Company in respect of the securities offered to the public according to the shelf offering totaled NIS 6,604 (proceeds net of issuance costs amounted to NIS 6,292).

Following the offering, the CEO and additional officers became entitled to a bonus, in accordance with the Company's compensation policy, totaling NIS 172. The Company accrued this amount as an expense in the second quarter of 2015. Pursuant to the issuance of the share capital, the Company granted 200,000 options (Series 1) exercisable for 200,000 ordinary shares of the Company to a broker, representing 0.26% of the Company's issued and outstanding capital on a fully-diluted basis, at an exercise price of NIS 1.85 per share, in consideration for NIS 32, which was recorded in the second quarter of 2015, as deduction from the share premium.

- During June 2015, 341,073 unlisted options were exercised for 341,073 shares of the Company, in consideration for a total of NIS 104.
- 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, Mr. Nuriel Kasbian Chirich, in the private placement, and accordingly he was allotted 287,769 shares and 95,923 unlisted warrants of the Company at the same terms of issue 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.
- On July 28, 2016 the Company completed a US initial public offering (the "IPO") on NASDAQ in which it raised gross proceeds of NIS 32,107, (NIS 25,820 net of all issuance costs, including share-based awards granted), including the Underwriters remuneration, through an issuance of ADS and warrants to ADS. An amount of NIS 23,269 out of the consideration was ascribed to net the ADS and classified as equity component, while an amount of NIS 3,173 was ascribed to the fair value of the Traded Warrants to ADS and was classified as a liability. Issuance costs amounting to NIS 622 associated with the issuance of the Traded Warrants to ADS, have been recognized as finance expenses in the operation report.

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**CELLECT BIOTECHNOLOGY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In thousands, except number of shares data**

**NOTE 13:- EQUITY (Cont.)**

The 969,231 Traded Warrants to ADS are exercisable at a 1:1 ratio, for a period of five years at an exercise price of US\$ 7.5 per warrant. Since the warrants' exercise price is in US dollars, which is not the Company's functional currency, the Traded Warrants to ADS were

Pursuant to the Underwriters agreement, the Underwriters purchased 1,292,308 ADS as well as 969,231 Traded Warrants to ADS at 1:1 ratio, at a price to the public of US\$ 6.5 per unit. Furthermore, the Company granted the Underwriters an option, exercisable within 45 days from the date of signing the underwriting agreement, to purchase up to 193,846 additional ADSs at a price of US\$ 6.038 per ADS and/or an additional 145,385 Traded Warrants to ADS at a 1:1 ratio, at the same terms as the warrants issued to the public, at a price of US\$ 0.007 per warrant, to cover over-allotments, if any. The Underwriters purchased 65,890 Traded Warrants to ADS. 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 granted the Underwriters 77,538 Non-Tradable Warrants to ADS at an exercise price of \$ 8.8 per warrant convertible at a 1:1 ratio and is exercisable for a period of four years. The Underwriters' Non-Traded Warrants were classified as a share based payment transaction in accordance with IFRS 2 and netted off the total consideration as issuance cost.

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.

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**CELLECT BIOTECHNOLOGY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In thousands, except number of shares data**

**NOTE 14:- 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.

b. Details on share options granted are provided below:

1. On August 26, 2015, the Company's shareholders, at a general shareholders' meeting approved a grant to each of the Company's directors, including the external directors, of 72,000 unlisted options, exercisable for 72,000 ordinary shares, no par value, and in total, 504,000 unlisted options exercisable for 504,000 ordinary shares, no par value, of the Company, representing 0.6% of the Company's issued and outstanding capital on a fully-diluted basis, at an exercise price of NIS 1.90 per share.

On October 19, 2015, and on November 28, 2016 the board of directors approved an increase to the unlisted option pool of 4,087,903 and 1,000,000 options respectively. As a result, the Company has a total of 8,500,000 unlisted options.

2. On October 15, 2015, the Company appointed Ronen Twito as the Deputy Chief Executive Officer and Chief Financial Officer (the "Deputy CEO and CFO"), effective November 3, 2015. On November 23, 2015, the Company's shareholders, at a general meeting of shareholders approved the 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 1.28 per share, representing 3.5% of the Company's issued and outstanding capital. The total benefit in respect of the grant calculated at the grant date was NIS 3,033. The terms of service also included a bonus plan based on, among others, future capital raising by the Company.

Following the attainment of targets in 2016, the Company included provision for grant of five monthly salaries. On October 27, 2016, the Deputy CEO and CFO resigned. 1,550,643 options that were not vested were forfeited.

3. On November 29, 2015, the Company's board of directors approved the grant of 80,000 unlisted options to the Company's VP Research and Development exercisable for 80,000 ordinary shares. The fair value of the options at the grant in accordance with the Black-Scholes model estimated a total of about NIS 81, that will be recognized as an expense over the Vesting Period of the options (three years).
4. On March 31, 2016, the Company's board of directors approved the grant of 600,000 unlisted options to a consultant exercisable for 600,000 ordinary shares at an exercise price of NIS 2.1 each. The options vest each quarter over a period of 24 months, pursuant to the Company's option plan. On September 1, 2016 the agreement between the Company and the consultant was terminated. According to the termination arrangement, 300,000 options were vested, while the other 300,000 were forfeited.
5. On May 31, 2016 the Board of Directors approved an allotment of 70,000 unlisted options to the Company's VP Research and Development, Dr. Amotz Nechushtan, at an exercise price of NIS 1.68 per option. The options are exercisable quarterly over a vesting period of three years, in accordance with the Company's share option plan.

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**CELLECT BIOTECHNOLOGY LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In thousands, except number of shares data**

**NOTE 14:- SHARE-BASED COMPENSATION (Cont)**

6. On October 27, 2016, the Company appointed new CFO, effective January 1, 2017. The terms of service included among others, a grant

of 1,936,503 options, exercisable for 1,936,503 ordinary shares, no par value, of the Company at an exercise price of NIS 0.819 per share. The options shall vest over a period of 36 months, with a three months cliff. The total benefit in respect of the grant calculated at the grant date was NIS 1,373, to be recognized over the vesting term.

- c. 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)
	2014	2015	2016	Year ended December 31, 2016
	NIS			U.S. dollars
Share-based payment settled by equity instruments	798	1,318	1,552	404
Total share-based compensation	798	1,318	1,552	404

- d. Activity during the year:

The table below includes the number of share options, and the weighted average of their exercise prices:

	2015		2016	
	Number of options	Weighted Average Exercise price NIS	Number of options	Weighted Average Exercise price NIS
	Outstanding at beginning of year	2,994,907	1.2450	5,764,866
Options exercised for shares	(341,037)	0.3	-	-
Options forfeited	(131,250)	1.4	(2,054,396)	1.43
Option Expired	-	-	(337,000)	1.42
Granted	3,242,246	1.382	2,606,503	1.14
Outstanding at end of year	5,764,866	1.374	5,979,973	1.25

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CELLECT BIOTECHNOLOGY LTD.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

### NOTE 14:- SHARE-BASED COMPENSATION (Cont.)

- e. The following table summarize information about the Company's outstanding and exercisable options granted to employees and consultants as of December 31, 2016:

Exercise price (Range)	Options outstanding as of December 31, 2016	Weighted average remaining contractual term (years)	Options exercisable as of December 31, 2016	Weighted average remaining contractual term (years)
0.001 - 1.35	3,451,462	8.9	1,012,747	8.7
1.35 - 1.8	1,796,511	7.7	1,413,179	7.7
1.8 - 2.1	732,000	5.4	480,000	3.7
	5,979,973	7.3	2,905,926	6.7

- f. Measuring the fair value of share options settled by equity instruments:

The Company shares data which is useful for measuring the fair value of the options under the Black-Scholes model, for the years ended December 31, 2015 and 2016, is as follows:

	2015	2016
Dividend yield (%)	0	0
Expected volatility of the share prices (%)	85.8%-87.5%	84.05%-91.58%
Risk-free interest rate (%)	2.26%-2.33%	1.04%-2.10
Expected life of share options (years)	10	4-10

According to the data above, the fair value of options granted in the years 2015-2016 was set to NIS 5,569 at the grant date.

### NOTE 15:- TAXES ON INCOME

- a. Corporate tax rates in Israel:

The Israeli corporate income tax rate was 25% in 2016 and 26.5% in 2015 and 2014.

In January 2016, the Law for Amending the Income Tax Ordinance (No. 216) (Reduction of Corporate Tax Rate), 2016 was approved, which includes a reduction of the corporate tax rate from 26.5% to 25%, effective from January 1, 2016.

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy

b. Final tax assessments:

The Company received final tax assessments through tax years 2010. Collect has no final tax assessments since its inception (year 2011).

c. Net operating carryforwards losses for tax purposes and other temporary differences:

As of December 31, 2016, the Company had carryforward operating losses amounting to approximately NIS 23,478.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In thousands, except number of shares data**

**NOTE 15:- TAXES ON INCOME (Cont.)**

The Company did not recognize deferred tax assets for carryforward operating and capital losses and other temporary differences because their utilization in the foreseeable future is not probable.

**NOTE 16:- CONTINGENT LIABILITIES AND COMMITMENTS**

a. Commitments

According to the terms of the agreement dated July 7, 2013, the Chairman of the board of directors will be employed on a half-time basis, and will be entitled to a monthly salary as follows: until a cumulative investment of total of \$2,000 is raised – NIS 10; when an investment between \$2,000 to \$4,000 is raised – NIS 15 and once a cumulative total investment of more than \$4,000 is raised – NIS 20. He will also be entitled to a bonus for capital raised by the Company, whereby for the first \$2,000 raised, he will be entitled to a bonus of 0.75% of the amount raised, and for amounts exceeding \$2,000, he will be entitled to a bonus of 1% of the amount raised (exceeding the first \$2,000). The bonus in respect of the capital amounts raised is limited to NIS 200.

Further to the investment described in Note 13a.1, during 2014, the Chairman of the board of directors received a bonus of NIS 166 and 34 NIS for the years 2014 and 2015, respectively, as a result of capital raised. In July 2016, as part of the terms of agreement, it was decided that the Chairman of the board of directors will be employed on a third-time basis, thus updating his monthly salary to NIS 30. In addition, in event of an IPO, the chairman of the board's salary would be increased to NIS 35. In August 2016, after the IPO, the salary of the Chairman of the board was increased accordingly. On July 24, 2016 the Company's shareholders, at a general meeting of shareholders approved the updated terms as above.

Following the attainment of targets in 2016, the Company included provision for grant to the Chairman of the board of directors at the amount of NIS 100.

2. Under the terms of the agreement dated July 7, 2013, the Company's CEO is entitled, through a company he owns, to monthly compensation of NIS 58.5, and after an investment of \$2,000 is raised, the monthly compensation will increase by 10%, and will increase by a further 10% when an additional cumulative total investment of \$2,000 will be raised. Commencing in January 2014, the CEO was paid as an employee rather than a contractor, with the Company's expense for his employment remaining unchanged. Following a \$15,000 investment in the Company in April 2014, the CEO's monthly gross salary was raised to NIS 54.5. The CEO is also entitled to social benefits, car and customary expenses of senior officers in the Company.

In addition to the aforementioned compensation, the CEO is entitled to a bonus as follows: for investment of \$1,000 – NIS 100, and additionally, for investments of between \$1,000 and \$2,000 – 0.75% of the cumulative amount raised; for investments that exceed \$2,000 – 1% of the amount exceeding \$2,000, up to a cumulative one-off payment of NIS 200.

Further to the investment described in Note 13a.1, the CEO received a bonus totaling NIS 166 during 2014. In addition, the CEO received a bonus during 2015 in the amount of NIS 100 in respect of his performance in 2014.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In thousands, except number of shares data**

**NOTE 16:- CONTINGENT LIABILITIES AND COMMITMENTS (Cont.)**

On May 6, 2015, the Company's general shareholders' meeting approved the 2015 Bonus Plan of up to five times the CEO's monthly salary, depending on operational results. Following the attainment of targets in 2015, the CEO received a bonus during 2016 in the amount of NIS 216.

On March 31, 2016, the Company's board of directors approved the 2016 Bonus Plan of up to five times the CEO's monthly salary, depending on operational results. Following the attainment of targets in 2016, the Company included provision for grant of five times the CEO's monthly salary in 2016.

In July 2016, as part of the terms of agreement, it was decided that the CEO's monthly salary will be updated to NIS 70. On July 24, 2016 the Company's general meeting of shareholders approved the updated terms as above.

3. On September 1, 2015, the Company signed a new lease agreement for new offices. The aforementioned lease agreement is for a minimum period of 3 years from the date of signing the agreement. Under this agreement, the Company will pay a monthly rental fee plus an administration fee of NIS 32.

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 finish the agreement before the end of the three years and will have to pay an exit fine between one to three months of lease. The future minimum monthly lease payments as of December 31, 2016 are

approximately NIS 11.

4. On November 23, 2016, the Company signed an agreement with Tel Aviv stock exchange ("TASE") in which TASE participates in payments to analyst companies who will review the company's result and publish professional analysis.

As of December 31, 2016, The Company paid NIS 71 and the Company will pay in the future an amount of NIS 183.

- b. Liens:

The Company provided a NIS 20 restricted bank deposit to secure credit card payments.

The Company provided a NIS 120 restricted bank deposit to secure the rent payment.

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CELLECT BIOTECHNOLOGY LTD.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In thousands, except number of shares data

**NOTE 17:- SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS**

- a. Research and development expenses:

	Year ended December 31,			Convenience translation (Note 2d)
	2014	2015	2016	Year ended December 31, 2016
	NIS			U.S. dollars
Salaries and related expenses	1,555	2,739	3,711	966
Professional services	400	746	1,044	271
Patents	169	326	409	106
Subcontractors (*)	146	538	534	139
Share-based payment	512	523	253	66
R&D related purchases	208	770	1,676	435
Other research and development costs	68	251	629	164
	<u>3,058</u>	<u>5,893</u>	<u>8,256</u>	<u>2,147</u>

(\*) Reclassified.

- b. General and administrative expenses:

	Year ended December 31,			Convenience translation (Note 2d)
	2014	2015	2016	Year ended December 31, 2016
	NIS			U.S. dollars
Salaries and related expenses	850	1,024	2,994	779
Directors' fees	269	358	318	83
Share-based payment	286	795	1,299	338
Professional services	762	1,367	2,074	539
Insurance	23	23	143	37
Travel abroad	-	201	124	32
Office expenses	161	235	466	121
Other	140	201	550	143
	<u>2,491</u>	<u>4,204</u>	<u>7,968</u>	<u>2,072</u>

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CELLECT BIOTECHNOLOGY LTD.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In thousands, except number of shares data

**NOTE 18:- LOSS PER SHARE**

	Year ended December 31,					
	2014		2015		2016	
	Weighted number of shares	Net loss attributed to Company's share-holders	Weighted number of shares	Net loss attributed to Company's share-holders	Weighted number of shares	Net loss attributed to Company's share-holders
		NIS		NIS		NIS

Number of shares and loss for the purpose of calculating basic and diluted loss per share	65,968,768	(5,551,000)	74,475,109	(10,171,980)	91,128,516	(15,317,501)
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**NOTE 19:- BALANCES AND TRANSACTIONS WITH RELATED PARTIES**

a. Related party balances

	December 31				Convenience translation (Note 2d)	
	2015		2016		Year ended December 31, 2016	
	Key management personnel	Other related parties	Key management personnel	Other related parties	Key management personnel	Other related parties
	NIS				U.S. Dollars	
Other payables	116	274	318	805	83	209
	<u>116</u>	<u>274</u>	<u>318</u>	<u>805</u>	<u>83</u>	<u>209</u>

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)
	2014		2015		2016		Year ended December 31, 2016
	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 2014, 2015 and 2016)	3	2,143	5	3,423	7	6,040	1,571

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CELLECT BIOTECHNOLOGY LTD.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In thousands, except number of shares data

**NOTE 19:- 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)
	2014		2015		2016		Year ended December 31, 2016
	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	3	514	2	444	-	-	-
Directors' fees	5	248	5	477	5	513	133
	<u>8</u>	<u>762</u>	<u>7</u>	<u>921</u>	<u>5</u>	<u>513</u>	<u>133</u>

d. Transactions with related parties:

	Year ended December 31,						Convenience translation (Note 2d)	
	2014		2015		2016		Year ended December 31, 2016	
	Key management personnel	Related parties	Key management personnel	Related parties	Key management personnel	Related parties	Key management personnel	Related parties
Research and development expenses	533	1,023	713	1,422	1,063	1,544	276	402
General and administrative expenses	316	785	921	811	2,317	1,116	603	290

Financing expenses	-	22	-	-	-	-	-	-
	849	1,830	1,634	2,233	3,380	2,660	879	692

e. Commitments

Regarding commitments with a controlling shareholder, see Note 16.a

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CELLECT BIOTECHNOLOGY LTD.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In thousands, except number of shares data

NOTE 20: SUBSEQUENT EVENTS

- On October 27, 2016, the Company announced the resignation of the current deputy CEO and CFO, and the appointment of a new CFO commencing January 1, 2017.
- On January 12, 2017, the Company announced that it had received a formal notice of allowance around a key method of treatment patent (Application No. 13/811,374) from the United States Patent & Trademark Office. The allowed claims relate to the engineering of regulatory immune cells with enhanced apoptotic activity to be used for immunomodulation for treating or preventing immune related disorders.
- On January 26, 2017, the Company's board of directors approved the grant of 250,000 and 100,000 options to the company CDO and to the QA Director respectively, exercisable for 250,000 and 100,000 ordinary shares at an exercise price of NIS 0.631 each. The options vest each quarter over a period of 36 months, with cliff of 3 and 12 months respectively pursuant to the Company's option plan.
- On February 14, 2017, the Company announced that it will file a petition with the Israeli court and seek the approval of the Company shareholders to voluntarily delist the Company's ordinary shares from the Tel-Aviv Stock Exchange (TASE) in accordance with section 350 to the Israeli Company Law. Should the petition be approved, all shareholders will retain their pro-rated holdings, as trading will migrate to the NASDAQ Stock Exchange in the US.
- On February 28, 2017, the Company's board of directors approved the grant of 438,000 options to the Company's employees exercisable for 438,000 ordinary shares at an exercise price of NIS 0.867 each. 25% of the options will vest after one year and the other 75% will vest each quarter over a period of 36 months that will start after 1 year from the grant date. In addition, the Company's board of directors approved the grant of 3,024,040, 1,442,729 and 306,000 options to the Company's CEO, to the Chairman of the board and to three directors respectively. Each option is exercisable for 1 ordinary share at an exercise price of NIS 1.2. The grant is subject to the approval of the share holders.

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EX-12.1 2 v462334\_ex12-1.htm EXHIBIT 12.1

Exhibit 12.1

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a) or 15d-14(a)

I, Shai Yarkoni, certify that:

- I have reviewed this Annual Report on Form 20-F of Collect Biotechnology Ltd.;
- 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;
- 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;
- 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)) [language omitted in accordance with Exchange Act Rule 13a-14(a)] for the company and have:
  - 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;
  - [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];
  - 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
  - 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
- 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:
  - 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
  - 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 23, 2017

/s/ Shai Yarkoni  
Shai Yarkoni



EX-12.2 3 v462334\_ex12-2.htm EXHIBIT 12.2

Exhibit 12.2

**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.;
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)) [language omitted in accordance with Exchange Act Rule 13a-14(a)] 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) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];
  - (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 23, 2017

/s/ Eyal Leibovitz

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 Eyal Leibovitz  
 Chief Financial Officer

EX-13.1 4 v462334\_ex13-1.htm EXHIBIT 13.1

Exhibit 13.1

**CERTIFICATION PURSUANT TO  
18 U.S.C. Section 1350**

In connection with the filing of the Annual Report on Form 20-F for the period ended December 31, 2016 (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 23, 2017

/s/ Shai Yarkoni

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 Name: Shai Yarkoni  
 Title: Chief Executive Officer

EX-13.2 5 v462334\_ex13-2.htm EXHIBIT 13.2

Exhibit 13.2

**CERTIFICATION PURSUANT TO  
18 U.S.C. Section 1350**

In connection with the filing of the Annual Report on Form 20-F for the period ended December 31, 2016 (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 23, 2017

/s/ Eyal Leibovitz  
Name: Eyal Leibovitz  
Title: Chief Financial Officer

EX-15.1 6 v462334\_ex15-1.htm EXHIBIT 15.1

Exhibit 15.1

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), of our report dated March 22, 2017, 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, 2016.

Tel Aviv, Israel  
March 23, 2017

/s/ Kost Forer Gabbay & Kasierer  
KOST FORER GABBAY & KASIERER  
A member of Ernst & Young Global



Wash 1 with wash buffer #1

In process

Donor  
Cell Donation

QC Test 1

Wash 1  
with wash buffer #1  
Wash 2  
with incubation medium

Cell count



Transfusion within 2  
hours via filter

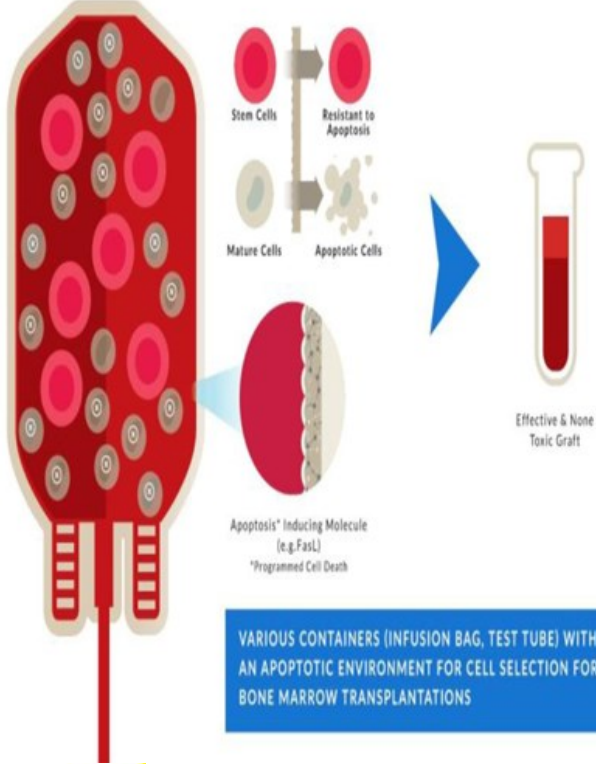
QC Test 2

Resuspension with  
Plasma-Lyte+5% HAS.  
Cell concentration  
100-200x10<sup>6</sup> cells/ml

Wash 3  
with wash buffer #1  
Wash 4  
with wash buffer #2

Incubation for 2 hrs  
with FasL, 37°C,  
5%CO<sub>2</sub>

**ApoTainer™**



VARIOUS CONTAINERS (INFUSION BAG, TEST TUBE) WITH AN APOPTOTIC ENVIRONMENT FOR CELL SELECTION FOR BONE MARROW TRANSPLANTATIONS

