UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934

For the month of January 2019
Commission File Number 001-37846

CELLECT BIOTECHNOLOGY LTD.

(Translation of registrant's name into English)

23 Hata'as Street
Kfar Saba, Israel 44425
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F x Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7): ☐

This Form 6-K (including Exhibit 99.1) is incorporated by reference into the registrant's Registration Statements on Form S-8 (Registration No. 333-214817, 333-220015 and 333-225003) and on Form F-3 (Registration No. 333-219614 and 333-212432).

Cellect Biotechnology Ltd. (the “Company”) is filing the information contained in Exhibit 99.1 for the purpose of updating certain aspects of the Company’s publicly disclosed descriptions of its business and risk factors. The disclosure updates are attached hereto as Exhibit 99.1 and incorporated by reference herein.

Exhibit

99.1 Disclosure Updates.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Cellect Biotechnology Ltd.

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

Date: January 24, 2019

Throughout this update, unless otherwise designated, the terms “we”, “us”, “our”, “Cellect”, “the Company” and “our Company” refer to Cellect 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 Cellect.

Overview

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

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

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

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

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

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

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

Our development efforts to date have primarily culminated in two studies performed on human HSCT grafts. The first study was performed during 2015-2016. In this study we used small portions received under ethical committee approval from human donors to validate and optimize the process, and show robustness and repeatability of the process. More than 100 ApoGraft samples were analyzed for the different effects on the various groups of cells (stem and mature immune) as well as their functional capabilities (such as migration, colony formation and anti-cancer activity). The samples represented 5% of a graft used for transplantation into patients. The grafts were processed in vitro and in vivo (mice) allowing stem cell production for transplantation using ApoGraft. The use of the ApoGraft resulted in a significant increase in the death of certain mature immune cells, primarily unique subsets of T Lymphocytes, without compromising the quantity and quality of stem cells.

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

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

We aim to commence a second human ApoGraft trial in the United States for patients with hematological malignancies in an allogeneic HSCT by the end of 2019. To this end, we plan to enter into a collaboration agreement with a leading academic institution to initiate the trial and are currently in advanced discussions with a leading academic institution. There can be no assurance that we will enter into any agreement with such institution. Previously, in May 2017, we announced that the FDA provided us with pre-Investigational New Drug (IND) meeting minutes supporting an IND submission for ApoGraft.

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

We expect to announce in the first half of 2019 pre-clinical results for the use of human fat derived stem cells treated with ApoGraft in orthopaedic treatments of animals. Furthermore, we plan on submitting an IND for the initiation of a Phase I/II trial of ApoGraft for anti-inflammatory and tissue engineering, such as shoulder rotator cuff tears that are common musculoskeletal injuries occurring mainly in aging populations.

Our Strategy

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

- **Leverage our scientific, clinical and regulatory expertise to build and advance our ApoGraft technology platform beyond the allogeneic HSCT setting.** Based on the validation of our ApoTainer selection kit for clinical use in the allogeneic HSCT setting, we intend to test the kit for other indications such as nonmalignant failures of the bone marrow (i.e. aplastic anemia), solid organ transplantation and auto-immune system disorders (such as Type 1 diabetes, Crohn’s disease, psoriasis and lupus). We also intend to develop our ApoGraft technology platform for other sources of stem cells (e.g., cord blood and fat) and other types of stem cells — most notably mesenchymal and neural. We believe that by expanding the various applications, sources and types of stem cells that can be used with our technology, we will establish broad use of our ApoGraft technology platform.

- **Build a diversified product portfolio**. Beginning with the development of our ApoTainer selection kit as a combination 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 ApoGraft based products for a broad spectrum of market segments, up to and including all production and research processes for stem cell based products. The pipeline of products is designed to address different markets beyond the clinical use such as products for research purposes and tools for manufacturing facilities for cell therapies and especially adult stem cells.

- **Selectively engage in strategic partnerships that establish our ApoGraft technology platform as the standard enabling technology for the enrichment of the stem cell population**. We ultimately seek to collaborate with other companies engaged in developing stem cell therapies. By incorporating our ApoGraft technology into their manufacturing process we will be able to significantly reduce their cost of manufacturing while improving the end products. As we believe our ApoGraft technology will significantly increase the yields of the first step of manufacturing (harvesting the stem cells) from any source of stem cells (i.e. blood, bone marrow, fat) and will result in a more purified bulk of stem cells, the next steps needed to reach the final products will be shorter, more efficient, less costly and result in a better product. In May 2018, we incorporated a US subsidiary and hired Andrew Sabatier as its Chief Business Officer to lead the business development activities from the US.

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

- **Pathway to first-in-human proof of concept**: We are currently enrolling patients to a Phase I/II study performed on cancer patients undergoing matched related allogeneic HSCT. This Phase I/II trial was approved by the Israeli Ministry of Health and is being conducted at the Rambam Medical Center and Hadassah Medical Center.

- **Pathway to product prototype**: We are engaged in developing prototypes of our ApoTainer selection kit. We demonstrated a proof of concept for the binding of the apoptotic protein to a polymer while preserving the protein's apoptotic activity. We tested a number of polymers and binding methods and selected the one best suited for manufacturing the stem cell selection kits.

- **Patent portfolio enhancement**: We are currently expanding our patent coverage from our current nine patent families and are applying for additional patents. By applying for additional patents for inventions created during development, we actively seek to widen and strengthen our patent portfolio. In addition, we are seeking relevant patents available for in licensing.

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

Regenerative Medicine and Cell Therapy

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

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

Regenerative medicine can be categorized into major subfields as follows:

- **Cell Therapy**. Cell therapy involves the use of cells, whether derived from adults, children or embryos, healthy donors or patients, from various parts of the body, for the treatment of diseases or injuries. Therapeutic applications may include cancer vaccines, cell based immune-therapies, arthritis, heart disease, diabetes, Parkinson's and Alzheimer's diseases, vision impairments, orthopedic diseases and brain or spinal cord injuries. This subfield also includes the development of growth factors and sera and natural reagents that promote and guide cell development.

- **Tissue Engineering**. This subfield involves using a combination of cells with biomaterials (also called “scaffolds”) to generate partially or fully functional tissues and organs, or using a mixture of technology in a bioprinting process. Some natural materials, like collagen, can be used as biomaterial, but advances in materials science have resulted in a variety of synthetic polymers with attributes that would make them uniquely attractive for certain applications. Therapeutic applications may include heart patch, bone re-growth, wound repair, replacement neo-urinary conduits, saphenous arterial grafts, inter-vertebral disc and spinal cord repair.

- **Diagnostics and Lab Services**. This subfield involves the production and derivation of cell lines that may be used for the development of drugs and treatments for diseases or genetic defects. This sector also includes companies developing devices that are designed and optimized for regenerative medicine techniques, such as specialized catheters for the delivery of cells, tools for the extraction of stem cells and cell-based diagnostic tools.

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

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.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risk factors set forth in our most recent Annual Report on Form 20-F on file with the SEC, as well as the following risk factors, which supplement or augment the risk factors set forth in our Annual Report on Form 20-F. Before making an investment decision, you should carefully consider these risks as well as other information we include in this Exhibit 99.1. The risks and uncertainties not presently known to us or that we currently deem immaterial may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment.

Risks Related to Our Financial Position and Capital Requirements

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

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

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

Since 2011, we have been focused on research and development activities with a view to developing our ApoGraft technology platform. We have financed our operations primarily through the sale of equity securities (both in private placements and in public offerings on the TASE and also on the Nasdaq) and have incurred losses in each year since our inception. We have historically incurred substantial net losses, including net losses of approximately NIS 28.2 million ($8.1 million) in 2017, NIS 15.3 million ($4.0 million) in 2016, and NIS 10.2 million ($2.6 million) in 2015 and NIS 16.3 ($4.5) million for the nine months ended 2018. As of September 30, 2018, we had an accumulated deficit of approximately NIS 80.3 million ($22.1 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, 2017 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we:

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

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

As of September 30, 2018, we had approximately NIS 23.4 million ($6.4 million) in cash and cash equivalents, a working capital of NIS 20.5 million ($5.6 million) and an accumulated deficit of NIS 80.3 million ($22.1 million). Based on our cash balances as of the date of this update, our management is of the opinion that without fund raising we have sufficient capital to finance our operations for up to seven months. We will need to raise significant additional capital, in one or more financings, and if we are unable to obtain additional sufficient financing, we will be forced to reduce the scope of, or eliminate our operations which would have a materially adverse effect on our business and results of operations.

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

Our future capital requirements depend on many factors, including:

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

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

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

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

Risks Related to Product Development and Regulatory Approval

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

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

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

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

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

We plan to bring our ApoTainer selection kits to market for HSCT as a combination product subject to the primary jurisdiction of Center for Biologics Evaluation and Research, or CBER. The classification of our ApoTainer selection kits by the FDA as a drug, a medical device or a combination product depends upon, among other things, the regulatory definition of a drug and a device, their primary mode of action and the indications for use or product claims. Based on informal discussions with the FDA concerning our regulatory plans, we believe the FDA will classify our ApoTainer selection kits as a combination product subject to the primary jurisdiction of the CBER. Accordingly, we expect the approval process of our ApoTainer selection kits to be more burdensome and lengthy than if our ApoTainer selection kits were classified as a combination product subject to the primary jurisdiction of the Center for Devices and Radiological Health. The cost and delay in the approval process could materially adversely affect our financial condition and results of operations and cash flows.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In September 2017, we announced that the FDA granted orphan drug designation for ApoGraft for the prevention of acute and chronic GvHD in transplant patients. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000 in the U.S.

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

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

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

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

Although we believe that our ApoGraft technology platform has broad application, because we have limited financial and managerial resources, we are currently focused on development of our ApoTainer selection kits for HSCT in order to demonstrate commercial viability of our technology platform. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

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

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

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

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

Any significant disruption in our supplier relationships could harm our business. We currently rely on a single source supplier for the apoptotis 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 have a sufficient supply of FasL for our ongoing Phase I/II trial however we will need to obtain an additional supply of FaSL for future planned clinical trials. We have experienced delays in the supply of FasL for our planned second human ApoGraft trial and are currently establishing a manufacturing process through a contract manufacturer to supply us with sufficient FasL for future planned clinical trials. If our current supplier or any other supplier suffers a major natural or man-made disaster at its manufacturing facility, or if they otherwise cease to supply to us, then this could result in further delays in our clinical studies and may delay product testing and potential regulatory approval until a qualified alternative supplier is identified. With respect to other raw materials for the ApoGraft technology platform, although alternative sources of supply exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers. If our manufacturers or we are unable to purchase any key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- attract parties for acquisitions, joint ventures or other collaboration;

- license proprietary technology that is competitive with ApoGraft technology platform or ApoTainer selection kits;
- attract funding; and
- attract and hire scientific talent and other qualified personnel.

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

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

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

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

Our board of directors has adopted a Code of Ethics which became effective upon the listing of our ADSs on Nasdaq. However, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

We rely upon patents to protect our technology.

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

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

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

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

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect us.

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

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain other developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to medical devices and biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. To date, we have not sought to enforce any issued patents in these foreign jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

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

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

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

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. In addition, the Israeli Supreme Court ruled in 2012 that an employee who receives a patent or contributes to an invention during his employment may be allowed to seek compensation for such contributions from his or her employer, even if the employee's contract of employment specifically states otherwise and the employee has transferred all intellectual property rights to the employer. The Israeli Supreme Court ruled that the fact that a contract revokes an employee's right for royalties and compensation does not rule out the right of the employee to claim their right for royalties. As a result, it is unclear whether and, if so, to what extent our employees may be able to claim compensation with respect to our future revenue. We may receive less revenue from future products if any of our employees successfully claim for compensation for their work in developing our intellectual property, which in turn could impact our future profitability.

Risks Related to Our Operations in Israel

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

Our head executive office, our research and development facilities, as well as some of our planned clinical sites, are or will be located in Israel. 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 have been growing in influence. Although ISIL's activities have not directly affected the political and economic conditions in Israel, ISIL's stated purpose is to take control of the Middle East, including Israel. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

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 benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished.

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

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

Since we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our articles of association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders of U.S.-based corporations. In particular, a shareholder of an Israeli company, such as us, has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards us and other shareholders and to refrain from abusing its power in us, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to our articles of association, an increase of our authorized share capital, a merger and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from discriminating against other shareholders. In addition, a controlling shareholder or a shareholder who knows that it possesses the power to determine the outcome of a shareholders vote or to appoint or prevent the appointment of an office holder of ours or other power towards us has a duty to act in fairness towards us. However, Israeli law does not define the substance of this duty of fairness. Since Israeli corporate law underwent extensive revisions approximately 15 years ago, the parameters and implications of the provisions that govern shareholder behavior have not been clearly determined. These provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on shareholders of U.S. corporations.

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

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

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

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

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

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

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

As of the date of this update, we have 500,000,000 authorized ordinary shares, out of which 130,414,799 ordinary shares are issued and outstanding, 41,492,550 are reserved for future issuance under outstanding options and warrants and under our 2014 Cellect Option Plan. Any equity financing necessary in order to fund our operations may require us to increase our authorized share capital prior to initiating any such financing transaction. Increasing our share capital is subject to the approval of our shareholders. In the event we fail to obtain the approval of our shareholders to such increase in our authorized share capital, our ability to raise sufficient funds, if at all, might be adversely effected.

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

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

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

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

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

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

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

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

- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting required by Section 404 of the Sarbanes-Oxley Act; and

- an exemption from compliance with any new requirements adopted by the PCAOB, requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about our audit and our financial statements.

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

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

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

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

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

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

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

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

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

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

- our failure to obtain the approvals necessary to commence clinical trials;
- results of clinical and preclinical studies;
- announcements of regulatory approval or the failure to obtain it, or changes or delays in the regulatory review process;
- announcements of technological innovations, new products or product enhancements by us or others;

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

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

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

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

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

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

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

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

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

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

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

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

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

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