

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549



FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2013

OR

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

For the transition period from _____ to _____

Commission File Number: 001-35112

Medgenics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

98-0217544
(I.R.S. Employer
Identification No.)

435 Devon Park Drive, Building 700
Wayne, Pennsylvania
(Address of Principal Executive Offices)

19087
(Zip Code)

(610) 254-4201

(Registrant's telephone number, including area code)

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

Title of each class	Name of exchange on which registered
Common stock, par value \$0.0001 per share	NYSE MKT
Redeemable common stock purchase warrants	NYSE MKT

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

The aggregate market value of common stock held by non-affiliates of the registrant, computed by reference to the closing price of the registrant's common stock on the NYSE MKT on June 28, 2013, as of the last business day of the registrant's most recently completed second fiscal quarter was \$61,660,779.80.

As of February 17, 2014, the registrant had 18,692,257 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be issued in conjunction with the registrant's annual meeting of stockholders to be held in 2014 are incorporated by reference in Part III of this Annual Report on Form 10-K. The proxy statement will be filed by the registrant with the Securities and Exchange Commission not later than 120 days after the end of the registrant's fiscal year ended December 31, 2013.

MEDGENICS, INC.
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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding the progress and timing of clinical trials, the safety and efficacy of our product candidates, the goals of our development activities, estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities to support our products, our expected further revenues, operations and expenditures and projected cash needs. These statements relate to future events of our financial performance and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. Those risks and uncertainties include, among others:

- our ability to obtain additional funding to develop our product candidates;
- the need to obtain regulatory approval of our product candidates;
- the success of our clinical trials through all phases of clinical development;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to commercialize our product candidates;
- market acceptance of our product candidates;
- competition from existing products or new products that may emerge;
- regulatory difficulties relating to products that have already received regulatory approval;
- potential product liability claims;
- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability and third parties’ abilities to protect intellectual property rights;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to adequately support future growth; and
- our ability to attract and retain key personnel to manage our business effectively.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as “can,” “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “continues,” “anticipates,” “intends,” “seeks,” “targets,” “believes,” “estimates,” “projects,” “predicts,” “potential,” or the negative of those terms, and similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including, but not limited to, those discussed in the section titled “Risk Factors” included in Part I, Item 1A of this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Any forward-looking statement speaks only as of the date of this report and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise. We qualify all of our forward-looking statements by these cautionary statements.

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the “Company”, “Medgenics”, “we,” “us” and “our” refer to Medgenics, Inc., a Delaware corporation organized on January 27, 2000, and its wholly-owned subsidiary, Medgenics Medical (Israel) Limited, a company organized under the laws of the State of Israel. We use Biopump™, EPODURE™, INFRADURE™, HEMODURE™, DermaVac™ and the Medgenics logo as service marks in the United States and elsewhere. All other trademarks or trade names referred to in this document are the property of their respective owners.

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PART I

ITEM 1 - Business.

We are a medical technology and therapeutics company developing an innovative and proprietary platform technology offering what we believe to be a novel approach for the \$50 billion orphan and rare diseases therapeutics market. Our Biopump Platform Technology converts a small piece of the patient's own dermal skin tissue into a protein- and/or peptide-producing "Biopump" to continuously produce and deliver therapeutic proteins and/or peptides, and—when implanted under the patient's skin—has the potential to deliver several months of protein/peptide therapy from a single procedure without the need for a series of frequent injections. While our focus is on developing and commercializing the Biopump in orphan and rare disease markets, the original proof of concept of our Biopump Platform Technology has been demonstrated using EPODURE, a Biopump producing erythropoietin (EPO) for anemia, which is attractive for this purpose due to an easily available patient population and robust clinical endpoints. Human studies have shown that the EPODURE Biopump results were safe, reproducible, and demonstrated the expected efficacy, and that EPO levels stayed within a normal physiological range. We are aiming to extend these results using a new viral vector and implantation improvements which have shown a 40-fold increase in protein production and greater than six months of protein production in our SCID mouse model, which has been historically predictive of human efficacy. The new viral vector and implantation procedure will be utilized in our ongoing human EPODURE trial, and upon success we intend to actively look to partner the EPODURE program for further development.

Our Biopump is a tissue micro-organ (MO) that acts as a biological pump created from a toothpick-sized piercing of the patient's dermal tissue to produce and secrete a particular protein or peptide. We have developed a proprietary device called the DermaVac to facilitate reliable and straightforward removal of MOs and implantation of Biopumps. With the DermaVac, dermis MOs are rapidly harvested under local anesthetic from just under the skin to provide unique tissue structures with long-term viability *ex vivo*. This procedure allows us to process one or more dermis MO (s) outside the patient to become Biopump protein producing units in nine days, each making a measured daily amount of a specific therapeutic protein or peptide to utilize in treating a specific chronic disease. Based on a patient's particular dosage needs, we can determine how many Biopumps to then insert under the patient's skin in order to provide a sustained dose of protein or peptide production and delivery for several months. We believe the dosage of protein/peptide can be reduced by simple ablation or excision of inserted Biopumps, or increased by the addition of more Biopumps to provide personalized dosing requirements according to each patient's individual needs. We have effectively demonstrated that MOs and Biopumps can be processed in individual sealed chambers which can then be viably transported by land and air, and are developing devices to automate and scale up the cost-effective production of Biopumps in local or regional processing centers.

We have produced more than 20,000 Biopumps to date which have demonstrated in the laboratory the capability for sustained production of therapeutic proteins, including EPO to treat anemia (EPODURE), interferon-alpha (INF- α) to treat various forms of hepatitis (INFRADURE) and Factor VIII clotting protein to treat hemophilia (HEMODURE). Through these programs, we have determined to begin focusing on orphan and rare diseases where we believe our technology will have the greatest impact. As a result of this focus, we have de-prioritized our INF- α and Factor VIII programs as we hone in on orphan and rare disease targets. The *in vitro* stability and simplicity in handling of the Biopump is a key feature separating Biopumps' tissue therapy approach from those of therapies based on individual cells grown in culture. Biopumps use the patient's own intact tissue, implanted subcutaneously where it heals in place. This *ex vivo* transduction and implantation of an intact tissue matrix reduces the risks of gene therapy by obviating the systemic exposure to the virus, while also allowing the option of excision or ablation if medically necessary.

We believe our Biopump Platform Technology may be best applied to produce an array of other therapeutic proteins and peptides from the patient's own dermal tissue in order to treat a wide range of rare and orphan diseases. We believe our personalized approach could replace many existing protein therapies, which use proteins produced in animal or human fibroblast cells administered by frequent injections over long periods of time. We are currently in pre-clinical testing with the Biopump in several rare and orphan diseases, and will identify the targets once the IP applications around the new technology have been applied.

Clinical proof of concept (POC) of the Biopump Platform Technology was reported in a phase I/II study using EPODURE Biopumps that produced and delivered EPO in patients with CKD to treat their anemia, with interim study results presented by leading nephrologists at major nephrology conferences in 2010 and 2011. A total of 19 patients were treated in our initial phase I/II study, with each patient receiving a single administration of multiple Biopumps of EPODURE at a specified low, medium, or high dose. The EPODURE administered was sufficient to maintain the patient's hemoglobin in the range of 9 to 12 g/dl without need for any injections of EPO for more than three months in 14 of the 19 patients, of whom eight remained in range for more than six months, the longest lasting more than three years. We and our advisors believe that the results in patients treated to date have demonstrated POC and the safety and efficacy of our technology so far in its first application: EPODURE for treatment of renal anemia associated with end stage renal disease. Based on the results of our phase I/II clinical study of the EPODURE Biopump and our other development and testing efforts for our Biopump Platform Technology, we obtained clearance from the U.S. Food & Drug Administration (FDA) for our Investigational New Drug (IND) application for a phase II study in the United States of EPODURE in treatment of anemia in patients on dialysis. However, based upon the previously mentioned *in vivo* results obtained through the use of a new viral vector and implantation protocol, we are in the process of amending the original U.S. and Israeli IND applications, and expect to begin this clinical trial in the first half of 2014.

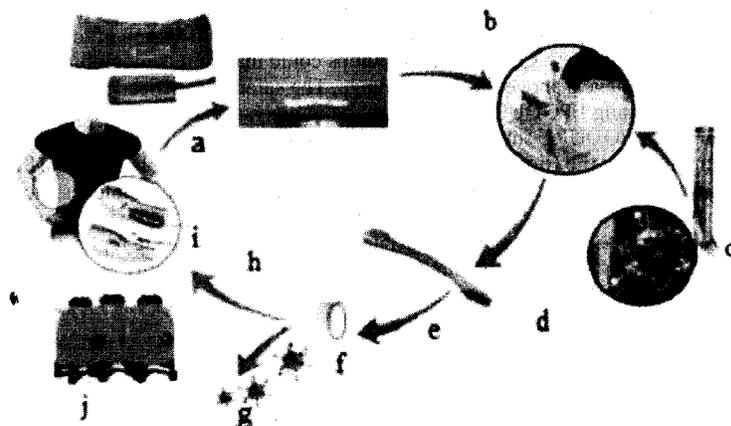
EPODURE Biopumps for the treatment of anemia have now been processed by our contract manufacturing organization (CMO) in a good manufacturing practice (GMP)-certified facility in the United States. This marks the first Biopump processing site outside of Israel, and provides us with a significant ability to scale-up our clinical and commercial capabilities to address global therapeutic areas such as rare and orphan diseases and anemia. In a key "dry run" test of the production system, tissue micro-organs were obtained and loaded into individual closed processing chambers in Israel, and then shipped to the U.S. CMO Biopump processing center in California. There, the micro-organs were processed within their closed systems into fully functioning EPODURE Biopumps, meeting the release criteria for use in human clinical trials in the United States and demonstrating our capability to support the treatment of patients at remote clinical sites by transporting their Biopumps to and from strategically-located processing facilities, thereby allowing for multicenter clinical trials and practical commercial implementation.

Based on our growing base of clinical- and pre-clinical results, we continue to seek collaboration with third parties in order to fully develop the EPODURE product candidate, while focusing on developing and leveraging our core technology in multiple rare and orphan disease areas. Limited development and commercialization costs, high reimbursement rates, and mandated governmental exclusivity make rare and orphan diseases attractive areas for a small biotech company. Initial approval/commercialization of our first product is not anticipated before 2017.

We believe that the Biopump Platform Technology has great potential to offer a better treatment alternative to current methods of protein therapy for rare and orphan diseases (which as stated can often involve years of frequent injections and significant side effects, including anaphylaxis and antibodies against the exogenous protein or peptide injections). We believe that the Biopump Platform Technology will provide a wide range of advantages over existing therapies, and appeal/offer many potential benefits to doctors, patients and third-party payers (e.g., Center for Medicare and Medicaid Services (CMS), medical insurers, etc.), including:

- Improved efficacy and safety due to autologous protein and/or peptide production.
- Elimination of frequent injections.
- Reversible treatment.
- More personalized medicine.
- Greater patient compliance.

The Biopump Platform Technology Process (Anticipated Automated Process)



- (a) *Harvesting Patient's Micro-organs (MOs)* – our proprietary device, the DermaVac, is used to extract a small piece of tissue via a form of needle biopsy from the skin's lower level – the dermis – of patient under local anesthesia. The DermaVac positions the skin and guides a high-speed rotating hollow core needle, providing a precise and straightforward removal of the tissue. This procedure is intended to be performed under local anesthetic. It is minimally-invasive, enabling rapid healing.
- (b) *Transfer to processing station* – after harvesting, the MOs are transferred to a Biopump processing center.
- (c) *Viral vector fluid* – a small amount of fluid containing the appropriate concentration of viral vector, which specific vector has been engineered to contain the gene necessary for production of a selected protein and to effectively transfer the gene to the nuclei of the cells in the MO without integrating into the chromosomes.
- (d) and (e) *Processing each MO into a Biopump* – in the Biopump processing center, MO (d) is processed using the viral vector fluid, whereby the vector particles transfer the genes into the cells of the MO (transduction), thereby converting the intact tissue MO into a Biopump protein/peptide production unit (e). The MOs are transferred at the harvest site in a sealed cassette and transported to local or regional Biopump processing centers. While processing is currently performed manually, we plan to develop semi-automated processing stations.
- (e) *Biopump producing desired protein*
- (f) *Measure daily protein production per Biopump for dosing* – protein production levels of the Biopumps are measured to determine the correct number of Biopumps to implant to deliver the intended aggregate dose to the subject patient.
- (g) *Washing and release testing* – prior to being released for use, the Biopumps undergo a washing protocol to remove most, if not all, of the residual unabsorbed vector and undergo testing to verify they meet the release criteria for use, generally nine days after harvesting.
- (h) *Transport to the treatment center* – the Biopumps are transported to treatment center for implantation in the patient.
- (i) *Implantation of the required number of Biopumps* – the calculated number of Biopumps are implanted back into the patient where they produce and deliver the required protein to the subject patient's body. Additional MOs or Biopumps not implanted in the patient can be cryostored for future use.
- (j) *Additional MOs or Biopumps not implanted in the patient can be cryostored for future use.*

Proof of Concept of Biopump Platform Technology

The concept of the Biopump has been demonstrated in both the clinic and the laboratory, beginning with the phase I/II clinical trial for our first product—the EPODURE Biopump—which was conducted in Israel under the regulatory jurisdiction of the Israeli Ministry of Health. This key study demonstrated that a single administration of a few EPODURE Biopumps could maintain hemoglobin levels in the target range for months in a majority of patients without raising serum EPO levels above the normal range. The safety and efficacy data from the phase I/II study formed a major part of our IND application for a study using EPODURE to treat anemia in dialysis patients in the United States, which was cleared by FDA in mid-2012. The study results from our first EPODURE study in patients showed that tissue Biopumps can provide safe and sustained protein therapy in patients, and successfully demonstrated the Biopump concept for the first protein – erythropoietin (EPO). The aforementioned data, coupled with new *in vivo* SCID mouse data with an improved viral vector and new implantation techniques showing clinically meaningful protein production for more than six months, have led to our plans of resuming the EPODURE human trial with the new vector and implantation techniques. Given that Biopump SCID mouse data has historically translated into human efficacy, a replication of the SCID mouse data in the human clinical trial would provide significant POC for the Biopump platform’s commercial viability (e.g. protein or peptide production for more than six months). Assuming successful results with the new vector and implantation techniques in our human EPODURE trial we intend to broaden our current partnering discussions for further development of the EPODURE platform.

Based on the positive data to date in EPODURE, we have initiated several pre-clinical Biopump programs in rare and orphan diseases. These diseases were identified in markets where the Biopump’s therapeutic and autologous characteristics and sustained protein production, would be particularly advantageous. Identified markets would include those where the injected therapeutic protein/peptide has a short half-life, or where the injected protein/peptide elicits a significant immune response, leading to side effects or decreased efficacy. We will identify these new markets for the Biopump after the new intellectual property (IP) is registered.

EPODURE Biopump for the Treatment of Anemia in CKD and Renal Failure

Our EPODURE Biopump is designed to provide a safer, more reliable, and more cost-effective anemia therapy, which we believe can better maintain hemoglobin within a defined safe range while also significantly reducing costs. According to a number of recent studies, there are increased risks of mortality and cardiovascular disease in connection with present EPO therapy, and the FDA has recently issued a Black Box Warning imposing new limitations on the amounts of EPO used in current anemia therapy. Reflecting these concerns, the FDA has further reduced the maximum recommended hemoglobin levels in these patients from 12 g/dl to 11 g/dl, effectively reducing the amount of EPO needed to elevate and maintain hemoglobin in the target range. The FDA is also concerned about the additional risks associated with the excessive peak EPO levels which typically reach up to 100 times the normal physiological range following each bolus injection of EPO in current anemia therapy. We believe all these concerns increase the safety advantage potentially offered by EPODURE to maintain hemoglobin levels within a relatively narrow therapeutic range while also keeping EPO serum levels within the normal range in the patient. We also believe EPODURE usage can improve patient compliance and quality of life, in addition to potentially reducing the healthcare costs of treating these same patients. This supports the critical need for a steadier EPO delivery method, which the EPODURE Biopump is designed to address.

Overall Orphan Disease Market and Current Therapeutic Treatment Platform

The worldwide orphan disease market was \$52 billion in 2012 and is expected to grow to \$82 billion by 2018 (EvaluatePharma). The orphan disease market is fragmented, with 240 products comprising the \$52 billion in 2012 sales. Over the past five years, big pharma companies have targeted the orphan disease space via licensing and acquisition, booking 70% of overall orphan disease sales following the 2009 acquisition of Genzyme by Sanofi-Aventis. Several aspects of the orphan disease market that underlie its attractiveness include: 1) High price and reimbursement of orphan drugs (\$200,000-\$500,000 per year with seven years of U.S. government-mandated exclusivity); 2) Low development costs and expedited regulatory review (generally less than 100 patients treated for FDA approval and expedited regulatory pathway versus conventional drugs); and 3) Attractive commercial model (small sales force (e.g., 60 reps) to drive significant sales and high profit margins due to low operating costs and high price per dose).

The current standard platform for protein/peptide production and delivery involves a highly complex and capital-intensive manufacturing process based on large-scale animal cell tissue culture and delivery in the form of frequent injections (due to the short half-life of recombinant proteins as described below). Protein manufacturing plants generally take several years and substantial capital to build, secure regulatory approvals, and bring into production. Once produced, the protein is typically distributed to—and stocked in—pharmacies and physicians' offices and administered by injection. Injections can be painful and costly, often cause unpleasant and/or dangerous side effects, and require frequent home healthcare nurse or doctor's office visits. As a result, treatments based on the administration of serial injections can suffer from poor patient compliance and therefore not work as intended.

Furthermore, recombinant proteins/peptides are typically metabolized (broken down) by the body very quickly and have a very short therapeutic life, ranging from a few minutes to a few hours. This means that, for many proteins/peptides, injections need to be taken at least once a week—and often even more frequently—to maintain necessary concentration in the blood within the therapeutic window, (i.e. above the minimum level required to be effective). It is widely known in the medical community that, below certain levels, the protein/peptide has no therapeutic effect. In order to keep protein/peptide levels in the blood above the minimum therapeutic level for as long as possible between injections, large bolus injections are typically administered. Although this can extend the time before the protein/peptide levels in the blood drop below the minimum therapeutic level (undershoot), it also causes initial levels to rise to many times above the maximum desired level (overshoot). Current therapies produce extended periods of overshoot, which can cause significant side effects, followed by undershoot, which leaves the patient under treated until the next injection. In the case of EPO for treating anemia, the overshoot can cause stimulation of the lining of the blood vessels, raising the risks of hypertension and release of emboli which can lead to stroke.

Competition for Protein Therapy Market

Our industry is subject to rapid and intense technological change. We face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in activities related to the treatment of disease based on protein therapeutics, both in the United States and abroad. Some of these competitors may be pursuing the development of drugs and other therapies that target the same diseases and conditions that we are targeting.

Many of our competitors have financial and other resources substantially greater than ours. In addition, many of these competitors have significantly greater experience in testing pharmaceutical and other therapeutic products, obtaining FDA and other regulatory approvals of products, and marketing and selling those products. Accordingly, our competitors may succeed more rapidly than us in obtaining FDA approval for products and achieving widespread market acceptance. If we obtain necessary regulatory approval and commence significant commercial sales of our product candidates, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited or no commercial-scale experience.

Many existing protein and peptide replacement therapies require frequent dosing of relatively large amounts of protein. Immune responses reduce the effectiveness of therapy and in some cases result in allergic reactions, some severe and even life-threatening. The Biopump approach may provide an effective alternative by providing continuous secretion of authentic human peptide/protein glycosylated by the patient's own cells and thus more like the patient's own native protein or peptide. Such proteins/peptides are expected to be less likely to provoke an immune response in patients – at least in those patients who express non-functional or inadequate concentrations of the molecule of interest. Introduction of a protein that is foreign to the patient may still provoke an immune response.

There are also new methods for delivering protein from implanted slow-release depots or other devices, through the skin, through inhalation or through “smart pills” that evade the digestive track. However, these all face the common problem of who will supply the expensive protein to be delivered, which will still be produced in cells other than the tissue of the patient. Most of the alternatives to bolus injection are aimed at reducing the traditional patient resistance to injections; however, these alternatives to date do not adequately deal with the challenge of peaks and troughs in between each administration and the need for high patient compliance over an extended period to sustain therapeutic levels. Longer-lasting versions of therapeutic protein/peptide have been achieved through alteration of the protein/peptide molecule itself and may offer the potential to reduce the number of injections, but still require administration every one to two weeks. These longer-lasting versions of proteins remain expensive to produce and run the risk of prolonging the overdosing period resulting from any given injection. New molecules mimicking the action of proteins have been approved, providing an inter-injection period of up to four weeks. We believe that the risk of adverse reactions will be reduced by delivering the natural protein produced by the patient’s own tissue as the Biopump aims to do as compared to delivery of a new molecule attempting to mimic the action of the natural protein.

We face competition within protein/peptide therapeutics, directly from established competitors using alternative protein manufacturing and delivery methods for EPO and in many orphan and rare disease areas respectively. We also face potential competition from more conventional forms of gene therapy if and when any of these become approved and adopted in clinical use. Gene therapy aims to provide or augment inadequate, nonfunctional or absent proteins that are associated with disease. In vivo gene therapy requires infusion of viral vector into the body. Alternatively, bone marrow cells may be transduced outside the body and the cells reintroduced after partial bone marrow ablations. These techniques seek to cure the patient with a single treatment. Repeat-dosing in the event that a patient does not initially receive an adequate response is considered dangerous at present. Moreover, it is currently impossible to remove or inactivate the gene in the event of an adverse reaction. Novel technologies using drug regulation of gene expression are being studied, but will be more complex than existing approaches.

The Biopump, in contrast, uses intact tissue at all times, so that the cells in the tissue never leave their natural matrix. Upon re-implantation, the tissue heals in place, so the cells remain in their matrix. As a result, they do not need to wander to find a place to connect, and remain within the tissue. In this way, dosing can be reduced or stopped by ablating or removing one or more Biopumps, which are typically implanted about a millimeter below the skin’s surface in a marked position. In a group of Biopumps prepared from the same patient, the daily protein production rate is generally very similar between individual Biopumps, and is measured before implantation in the patient so that the total administered daily dose is known, as is the location of each Biopump. Furthermore, since no viral vector is applied to the patient in treating with Biopumps, we believe that the patient can be treated multiple times without the risk of developing rejection, unlike direct gene therapies. Biopumps thus address the key limitations of gene therapies in knowing the dose administered, in the ability to increase or reduce that dose, and most importantly, in being able to effectively stop the process if needed.

Business Strategy

Our primary strategy is two-fold: 1) Validate the Biopump platform technology with the new viral vector and implantation techniques through the current human EPODURE trial and partner the asset for further development; 2) Target the Biopump platform to attractive orphan and rare disease markets which we believe we could then independently develop and commercialize.

We plan to utilize the new viral vectors and implantation procedures for our human EPODURE clinical trials scheduled to begin in the first half of 2014. Assuming positive clinical results are achieved (i.e. protein production more than 6 months), we will then look to partner the program for further development. We are currently in discussions with potential partners awaiting the EPODURE clinical data with the new viral vector and implantation procedures.

In the first quarter of 2014, we have initiated several pre-clinical Biopump programs in orphan and rare diseases. The diseases were identified in markets where the Biopump’s therapeutic characteristics, autologous and sustained protein production, would create a clinically meaningful difference for the patient. Identified markets would include those where the injected therapeutic protein or peptide has a short half-life, or where the injected protein/peptide elicits a significant immune response, leading to significant negative side effects or decreased efficacy. We will identify these new Biopump markets after the new intellectual property (IP) is registered. In some cases, we will seek orphan drug status from the FDA and/or the European Medicines Agency (EMA).

The Biopump platform offers significant advantages in obtaining POC data in orphan disease markets including: 1) No significant capital expenditure to build a protein bioreactor or produce GMP protein for clinical trials; 2) SCID mouse and human tummy-tuck skin models whose historical results have translated into human efficacy; and 3) Creating the DNA constructs and viral vectors to known orphan disease targets is time and cost efficient.

Additionally, there are several aspects of the orphan disease market which underlie its attractiveness and would potentially allow us to independently develop and commercialize in specific orphan markets including: 1) High price and reimbursement of orphan drugs (\$200,000-\$500,000 per year with seven years of U.S. government-mandated exclusivity); 2) Low development cost and expedited regulatory review (generally less than 100 patients treated for FDA approval and expedited regulatory pathway versus conventional drugs); 3) Attractive commercial model (small sales force (e.g., 60 reps) to drive significant sales and high profit margins due to low operating costs and high price per dose).

In addition to developing new protein applications of the Biopump, we are also working towards practical scale-up and commercial implementation of Biopump treatment technology. In collaboration with outsourced engineering firms, we have developed a closed chamber system where each Biopump resides in its own sealed chamber within which it produces protein in a manner similar to the open system used to date. We have demonstrated and validated that Biopumps produced in the closed chamber are comparable to those processed in the previous open system. This key step led to the establishment of our first contract manufacturing center for the GMP production of Biopumps in the United States (located in Sacramento, CA). Prior to this, all of the Biopumps were produced in Israel, which involved manually processing the MOs into Biopump in GMP quality clean rooms. This approach results in a higher cost of processing as compared to the eventual commercial method anticipated in which processing is to be performed by semi-automated bioreactors using sealed cassettes. The limited availability of such facilities and the high levels of expertise required to manually produce Biopumps in accordance with strict GMP standards would limit the practical ability to perform clinical trials in multiple centers. GMP clean rooms are required to prevent accidental agent introduction and cross contamination and ensure that accurate results are obtained. This is acceptable for purposes of proving the Biopump concept in early clinical trials, and possibly for rare disease applications, but for larger clinical trials and commercial implementations, an automated processing system using closed cassettes is being developed.

Accordingly, we trained the personnel at the contract manufacturing center to use our proprietary processing chambers and associated devices to successfully implement the Biopump processing procedure. We demonstrated that this center could process Biopumps from remote sites: skin dermis micro-organs harvested into the sealed chambers in our plant in Israel were sent to the California processing center using a small battery powered portable incubator shipped via standard courier, and were correctly processed by the center into successful Biopumps meeting our release criteria. We believe that the practical demonstration of remote processing from a harvest site 9,000 miles overseas effectively demonstrates that such centers could service many clinical sites around the United States or elsewhere. The center in California is aimed to support manual GMP production of Biopumps for use in future U.S. Biopump clinical studies. Additional similar centers could be established in various geographical locations as needed. We continue to make improvements to the initial design of the chamber and plan to incorporate it into a closed, single-use cassette for the Biopumps from the patient. The practical implementation of the Biopump system will take advantage of the robustness and stability of the MOs and Biopumps for practical logistical transport using standard shipping means.

Regulatory Strategy

Our overall regulatory strategy is aligned with our main business strategy of partnering the EPODURE program after successful human clinical trials with the new viral vector and implantation techniques, and independently developing the Biopump for orphan and rare disease indications. The general path towards U.S. regulatory approval of a Biopump product is:

1. Select disease condition and protein therapeutic for application for FDA approval
2. Conduct pre-pre-IND (Investigative New Drug application) meeting with FDA to clarify preclinical requirements and outline of the clinical protocol
3. Collect preclinical data, and pursue either
 - a. Non-U.S. phase I/II: obtain approval by Israeli Ministry of Health, or equivalent in other country
 - b. U.S. phase I/II: present to a pre-IND meeting with FDA, complete IND and obtain FDA clearance to conduct phase I/II for the selected disease condition
 - c. In some cases, we will seek orphan drug status from the FDA

4. Conduct the phase I/II study, with some preference in Israel, where our team can provide maximal support
5. Conduct a pre-IND meeting with FDA based on the results of the phase I/II study, to determine what further clinical trials would be required in the diseases of interest
6. Submit IND for FDA prescribed studies (e.g., phase II/III as an extension of phase I for orphan and rare disease conditions) in the United States based on data of the phase I/II for the selected disease condition, supportive data from previous Biopump clinical trials, and preclinical and in vitro data
7. Obtain FDA clearance and proceed to conduct prescribed studies in the United States (and possibly internationally)
8. Submit BLA (Biologic License Application) for product sales

We are currently in step 6 for our first product candidate (EPODURE), having attained clearance from the FDA for a phase II trial in treating dialysis patients with ESRD in the United States. We believe that the shortest path through regulatory approval for the first Biopump application in the United States may be for a disease condition that has an orphan drug designation granted by the FDA, particularly a life-threatening disease. In the United States, the FDA has the authority to grant a special "orphan drug designation" to a drug or biologic product that treats a rare disease or condition, which orphan designation provides additional rights to approved products as well as requiring smaller clinical trials than for large indications. Diseases thought to affect less than 200,000 patients in the United States are typically deemed to be rare. As discussed earlier, we are currently involved in several pre-clinical studies with the Biopump in orphan diseases in which sustained, autologous protein/peptide production would offer an advantage.

An initial approval of a Biopump product candidate by the FDA will help establish the safety and efficacy of Biopumps as treatment for chronic diseases. Biopumps for other disease conditions will still need to prove their safety and effectiveness in a specific clinical indication in order to obtain future regulatory approval, but we believe the general questions on the safety and practicality of Biopumps as a treatment modality will become less of an issue at such point.

We are currently focused on seeking FDA approval initially as the U.S. market for therapeutic proteins is the largest. We also believe that the Biopump offers unique advantages addressing key issues of urgent importance in the U.S. market, such as cost-effectiveness, preventive treatment, and patient compliance. In preparation for our initial phase I/II EPODURE clinical trial in Israel, we were guided by our regulatory advisors (which include former FDA officers), in coordination with the FDA's preclinical department in the design of the requisite preclinical testing for approval of the trial. The study itself was approved by Israel Ministry of Health, and was performed in adherence with the International Conference on Harmonization (ICH) E6 Guidance for Clinical Practice. This is an international ethical and scientific standard for designing, conducting, recording and reporting clinical trials. The guidance defines unified standards for clinical data that will be acceptable to the European Union, Japan and the United States. We intend to conduct our future trials in such manner as well. It is anticipated that such offshore phase I/II studies will provide support for the registration process of EPODURE in the United States, which will involve additional clinical trials leading up to approval for sale.

Indeed, the FDA accepted the results of our phase I/II EPODURE study in patients with CKD in our IND application, which the FDA cleared for further human clinical studies in the United States in dialysis patients with ESRD disease, a more advanced renal failure than the CKD patients had in the phase I/II study. Prior to that, we presented our proposed study protocol, together with the scientific and clinical background, to the National Institutes of Health (NIH)'s Recombinant DNA Advisory Committee (RAC) for its review. RAC unanimously recommended proceeding with the proposed phase II study.

Our understanding from the FDA is that the Biopump Platform Technology is considered a combination product (being a combination of biological products and devices), with the primary mode of action being a biologic. This was borne out in the pre-IND meeting we held in August 2012, where the Center for Biologics Evaluation and Research (CBER) division of the FDA led the review of our EPODURE product candidate, with support from the Center for Devices and Radiological Health (CDRH) for the device aspects of the Biopump product candidate. Representatives of both CBER and CDRH subsequently reviewed the IND submission and cleared the phase II study in dialysis patients.

EPODURE Biopump Clinical Trials: Anemia in patients with CKD

We began our initial phase I/II trial of EPODURE for the treatment of chronic renal anemia at Hadassah Medical Center in 2008 under approval of the Ethics Committee of Hadassah Medical Center and the Israel Ministry of Health. In April 2010 we received further approval to add an additional site of Tel Aviv Sourasky Medical Center to the clinical trial. The study was a phase I/II, open label, dose escalation study, comprising three EPODURE sustained dosage groups of EPO (approximately 20, 40, and 60 IU/kg/day) for the treatment of anemia in CKD patients (stage III - IV), starting with the lowest dose. These dose levels were selected to roughly correspond to the FDA recommended dosing range for injected EPO from 50 to 150 IU/kg given three times per week, corresponding to 150 - 450 IU/kg per week, or 20 - 60 IU/kg per day.

CKD patients diagnosed as having renal anemia (i.e., having insufficient hemoglobin levels associated with reduced production of EPO by the failing kidneys) were candidates for the study, whether the patient was already under treatment for the anemia by a regimen of EPO injections (EPO dependent), or had yet to commence such a treatment (EPO naïve). Each patient was treated with a group of his or her own subcutaneously implanted Biopumps that were measured before treatment to produce the requisite aggregate amount of EPO per day (20, 40, or 60 IU/kg) based on the patient's weight. The treatment rationale was that by producing and delivering EPO continuously for a sustained period, Biopumps should help stabilize the patients' hemoglobin levels, and if the EPODURE Biopump dose was adequate for the patient's specific needs, the hemoglobin level would also be maintained in the target range of 10 - 12 g/dl – the range preferred by FDA at the time of the phase I/II study in 2008-12.

Under the approved protocol, ten dermis micro-organs were harvested from each patient by simple needle biopsy performed under local anesthesia using our proprietary device, the DermaVac, typically from the dermis of the abdomen. These tissues samples underwent a standardized, reproducible procedure in a GMP cell processing laboratory over the course of two weeks to convert them into EPODURE Biopumps which each secrete a measured and sustained amount of EPO per day. A group of the patient's Biopumps which together produce the dose of EPO required by the protocol was subsequently implanted back into the patient subcutaneously, again under local anesthesia.

The mid dose was administered after submission and approval of a safety report on the first six patients treated at the low dose. Likewise, we commenced high-dose administration following review of mid-dose data and approval by the IRB of Tel Aviv Medical Center. No related serious adverse events were reported for any of the treated patients, with the exception of minor, local subcutaneous hematoma (bleeding) seen at the harvest and implantation sites, as can be expected for any invasive procedures dealing with the skin. The hematoma was generally seen to clear up within several weeks for all patients treated. In addition, no immune response to the implanted Biopumps was reported. Because the protein secreted by the implanted Biopumps is the patient's own naturally-produced human EPO and not a foreign substance, no adverse reaction was expected, and none has been noted. Evidence that the Biopumps were not rejected by the patients' immune systems is seen in the sustained elevation and maintenance of hemoglobin levels in most of the patients. All of the patient procedures were well tolerated and no complaints of discomfort were received.

For the patients who were treated with EPO injections prior to the study, their treating physicians discontinued EPO injections at least four weeks prior to the day of Biopump implantation, as required in the approved protocol.

In November 2012, the summary results of the completed dose escalation study in CKD patients and initial results of our phase I/II in ESRD patients were presented at the annual meeting of the American Society of Nephrology. Data summarized from the completed CKD trial indicated that five of seven patients at the low dose level of 20 IU/kg/day, seven of seven patients at the mid dose level of 40 IU/kg/day, and two of five patients at the high dose level of 60 IU/kg/day avoided the use of supplemental EPO for three months or longer, and three of seven, five of seven, and one of five patients (respectively) avoided the use of supplemental EPO for six months or longer. In these treated patients, EPO levels were quickly elevated by 10-50 mU/ml above baseline with a generally larger net rise attained in proportion to the implanted dose and resulting in an increase in the number of new red blood cells (reticulocytes). The FDA issued a new guidance in 2011 indicating that hemoglobin should be maintained below 11 g/dl and high enough to avoid the need for increased transfusions, but not necessarily above 10 g/dl. In view of this new guidance, we note that the results of the completed study in 19 CKD patients showed that a single EPODURE administration elevated and maintained Hb levels above 9 g/dl for at least three months in 14 of 19 patients, and for at least six months in nine of them, without need for any transfusions or EPO injections.

Our proposed EPODURE clinical trial, with the previously discussed new viral vector and new implantation techniques, will seek to replicate and improve on the results of the phase I/II clinical trial including:

- Reliable preparation of Biopumps processed in sealed chambers;
- Demonstration of hemoglobin maintenance within the new specified range of 9-11 g/dl for more than six months from a single administration in typical patients;
- Avoidance of supraphysiological levels of serum EPO throughout the treatment (except when isolated EPO injections may be applied to treat a transient incident such as an inflammation or bleed); and
- Requiring fewer interventions during the specified time interval (currently planning for a more than six month duration).

If the proposed clinical study produces the anticipated results, we would look to further develop/commercialize the EPODURE platform with a strategic partner(s). Details of any subsequent clinical trials will only be determined by the FDA upon review of the results of the data from our planned clinical study.

Other Clinical Trials and Pre-Clinical Studies

We began an approved study of our INFRADURE Biopump which produces INF- α for the treatment of patients with hepatitis C and treated the first patient in Israel in 2013. The initial INFRADURE results were consistent with the EPODURE phase I/phase II results and showed a reduction of 103 from baseline in the hepatitis C virus viral load. This trial did not use the next-generation viral vector or improved implantation techniques to be used in our forthcoming EPODURE trial. We also obtained an orphan drug status from the FDA for INFRADURE for use in treating patients with hepatitis D, although we have not yet pursued pre-clinical research in such indication. Development of INFRADURE has been placed on hold as we focus our resources on: 1) The validation of the Biopump platform through the human EPODURE trial with next generation viral vector and new implantation techniques; 2) Development of orphan and rare disease applications for the Biopump.

During 2010-2011, we performed pre-clinical studies of our HEMODURE Biopump which produces Factor VIII for the treatment of patients with hemophilia, in collaboration with Baxter Healthcare, a market leader in the field of hemophilia. We are continuing our pre-clinical work on the Factor VIII protein.

Intellectual Property

Our goals are to obtain, maintain, and enforce patent and trademark protection for our products, processes, methods, and other proprietary technologies of the Biopump Platform Technology, and to preserve our trade secrets both in the United States and elsewhere in the world. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our Biopump Platform Technology through a combination of contractual arrangements, trade secrets, patents, and trademarks both in the United States and abroad.

Our ability to compete depends on our ability to maintain and enforce our intellectual property rights and operating without infringing the intellectual property of others and our ability to enforce our licenses. Our business could be materially harmed and we could be subject to liabilities because of lawsuits brought by others against our licensors and licensees with whom we have a strategic alliance. We will be able to protect our technology from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are an essential and material element of our business.

Our existing owned and licensed patent portfolio directed to Biopump Platform Technology, and EPODURE currently contains 49 issued and 58 pending patents. Applications for patents and other intellectual property rights capable of being registered have been, and will be, filed in certain key jurisdictions. As we identify orphan and rare disease targets, we seek protection for the related intellectual property rights in the United States and other relevant jurisdictions.

Our licensed and owned patent portfolio covers the key elements of the Biopump Platform Technology, ranging from tissue engineering to device implementation and systematic treatment. Our patent portfolio includes our proprietary dermal genetically modified micro-organ Biopump Platform Technology which includes the EPODURE Biopump and production, processing, implantation and the tools designed for use in the Biopump procedure.

For dermal micro-organs, genetically modified dermal micro-organs and uses thereof, tools for harvesting and implanting dermal micro-organs/genetically modified dermal micro-organs and use thereof, and tools for producing genetically modified micro-organs for the Biopump Platform Technology, we have issued patents and pending patent applications in the United States, Australia, Canada, China, Europe (genetically modified dermal micro-organs and uses thereof is validated in Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Estonia, Spain, Finland, France, United Kingdom, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, The Netherlands, Poland, Portugal, Romania, Sweden, Sweden, Slovakia, Turkey, Albania, Croatia, Lithuania, Latvia and Macedonia; tools for producing genetically modified micro-organs is validated in France, Germany, Ireland, Luxembourg, Monaco, Netherlands, Switzerland & Liechtenstein, and Great Britain) Hong Kong, India, Israel, Japan, South Korea and Mexico. The patents issued in the United States for genetically modified dermal micro-organs and uses thereof will expire between April 2024 and September 2027, depending on the specific claims. The patents issued outside of the United States for genetically modified dermal micro-organs and uses thereof, tools for harvesting and implanting and tools for producing a genetically modified micro-organ will expire between November 2022 and September 2027, depending on the specific claims. The expected patent term is between November 2022 and September 2027 for patent applications pending in the United States and in the rest of the world, depending on the specific claims. For EPODURE and uses thereof, we have issued patents and pending patent applications in the United States, Australia, Canada, China, Europe, Hong Kong, India, Israel, Japan and South Korea. Further, we have a pending International Application (PCT) directed to use of EPODURE for treating anemia. The patents issued in the United States for EPODURE and uses thereof will expire between April 2024 and September 2027, depending on the specific claims. The patents issued outside of the United States for EPODURE and uses thereof, will expire between April 2024 and September 2027, depending on the specific claims. The expected patent term is September 2027 for patent applications pending in the United States. The expected patent term is between April 2024 and September 2027 for patent applications pending in the rest of the world.

A number of the patents and patent applications pertaining to the Biopump Platform Technology are licensed under an exclusive, worldwide license from Yissum Research Development Company of the Hebrew University of Jerusalem (Yissum). For micro-organs, genetically modified micro-organs, and micro-organ technology as described in the Yissum registered patents and pending patent applications, we have an exclusive license from Yissum under its issued patents and pending patent applications in the United States, Australia, India, Israel, South Korea and Singapore, covering the composition of matter of genetically modified micro-organs (Australia; Israel; Korea; Singapore), methods of making a genetically modified micro-organ (India; Israel; Singapore), and methods of use of a genetically modified micro-organ (United States; Australia; Israel; Singapore). The patent that we licensed from Yissum and issued in the United States for a method of delivering a gene product to a recipient, which includes the step of implanting a skin micro-organ expressing at least one recombinant gene product, will expire June 24, 2022. The expected patent term is July 9, 2022 for the patent application we licensed from Yissum, which is pending in the United States for validating a target candidate therapeutic molecule. The patents we licensed from Yissum and issued outside of the United States for genetically modified micro-organs, preparation thereof and use thereof, expire October 23, 2021 and June 22, 2020, depending on the specific claims. We have pending patent applications in Israel for genetically modified micro-organs that, if issued, would expire October 23, 2021.

A number of the patents and patent applications pertaining to Factor VIII variants are licensed under an exclusive, worldwide license from the University of Michigan. For Factor VIII variants and vectors thereof comprising the Chinese hamster elongation factor 1a promoter described in the University of Michigan registered patents and pending patent applications, we have an exclusive license within the licensed scope for isolated nucleic acids encoding Factor VIII variants and vectors thereof, and for recombinant Factor VIII protein variants and methods of production thereof, from the University of Michigan under its issued patents and pending patent applications in the United States, Europe, Australia, Canada and Japan. The patents that we licensed from the University of Michigan and issued in the United States for Factor VIII protein variants will expire between April 2017 and May 2018, depending on the specific claims. The expected patent term is between April 2017 and June 2027 for the patent applications we licensed from the University of Michigan, which are pending in the United States for Factor VIII variants and vectors thereof, depending on the claims thereof. The patents that we licensed from the University of Michigan and issued outside of the United States for Factor VIII variants and vectors thereof expire between April 2017 and June 2027, depending on the specific claims. The patent applications that we licensed from the University of Michigan and are pending outside of the United States for Factor VIII variants and vectors thereof are expected to expire between April 2017 and June 2027, depending on the specific claims.

There can be no assurance that the pending applications will result in patents ultimately being issued.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary knowledge and experience that is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements with our employees, consultants, vendors, collaborators, advisors, customers and other third parties to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials. We intend to continue to take all appropriate steps to protect our intellectual property, including maintaining an active program for patent protection for novel elements in the development of our products and technology.

Licenses

Yissum license

The licensing arrangements with Yissum formally commenced in 2000 and have since been replaced by the current arrangements prescribed by a License Agreement, which was entered into on November 23, 2005. The Yissum license is for a term that expires on the later of:

- 20 years from the date of making the first commercial sale of any product utilizing Yissum's technology under the Yissum license; and
- the expiration of the last Yissum patent licensed to us, which is expected to be approximately July 2022.

The scope of the Yissum license includes the exploitation of MO and MO technologies in the development and implementation of gene therapy for use in the prevention, treatment and diagnosis (or curing) of disease and for producing recombinant proteins or nucleic acids for therapeutic applications. Under the Yissum license, we agreed to pay Yissum the following amounts:

(a) three fixed installments measured by reference to investment made in our company, as follows:

1 st installment -	\$50,000 shall be paid when the cumulative investments in our company by any third party or parties, from May 23, 2005, amount to at least \$3 million which was paid in 2007.
2 nd installment -	Additional \$150,000 shall be paid when the cumulative investments in our company by any third party or parties, from May 23, 2005, amount to at least \$12 million which was accrued as of December 31, 2009 and paid in 2010.
3 rd installment -	Additional \$200,000 shall be paid when the cumulative investments in our company by any third party or parties, from May 23, 2005, amount to at least \$18 million which was triggered by the closing of our U.S. IPO and paid in April 2011.

- (b) royalties at a rate of 5% of net sales of the product; and
- (c) sublicense fees at a rate of 9% of sublicense considerations.

The Yissum license provides that our total aggregate payment of royalties and sublicense fees to Yissum shall not exceed \$10,000,000.

We are required to carry out development of the product according to a written plan and timetable approved by our Board and as may be updated from time to time. Upon completion of development, we are required to perform all actions necessary to seek effective commercialization and maximize net sales. The Yissum license requires that we reimburse Yissum for the costs and expenses of prosecuting the pending patent applications and of maintaining all registered patents licensed to us. If, however, for reasonable commercial considerations, we decide that we do not wish to fund the registration or maintenance of a patent in a certain state or country and Yissum applies for, registers or maintains a patent covered by the Yissum license in that state or country at its own cost, the patent license with respect to that state or country will revert to Yissum and be capable of being licensed to a third party or exploited by Yissum. In addition, if the Yissum license ends or is terminated for any reason, all rights in the Yissum patents will revert to Yissum.

BCM license

We also have licensed from Baylor College of Medicine (BCM) the non-exclusive right to use technology developed by BCM in producing the HDAd (gutless adenoviral vector). Under the BCM License, we agreed to pay the following amounts:

- (a) a one time, non-refundable license fee of \$25,000 which was paid in 2007;
- (b) an annual non-refundable maintenance fee of \$20,000;
- (c) a one-time milestone payment of \$75,000 upon FDA clearance or equivalent of clearance for therapeutic use; and
- (d) \$25,000 upon our execution of any sublicenses in respect of the BCM technology.

The BCM license commenced on January 25, 2007 and was amended on December 19, 2013 (and references collaboration agreements between us and BCM dated January 25, 2006, April 6, 2006, January 30, 2007, February 4, 2007, January 25, 2010 and October 27, 2013). The BCM license provides that the commercial use of any invention, product or process derived from research materials used in the collaboration thereunder will also be subject to the BCM license. The BCM license expires on the first date following the tenth anniversary of our first commercial sale of products incorporating the BCM licensed technology. After the BCM license expires, we will have a perpetual, non-exclusive, royalty free license to the licensed BCM technology. If we fail to make the payments due or otherwise breach our obligations under the BCM license agreement, BCM would have the right to terminate the BCM license agreement. If the BCM license is terminated, the rights to the licensed technology (except our developed technology) will revert to BCM.

University of Michigan license

We have entered into a worldwide licensing agreement of certain patents relating to nucleic acid sequences encoding variants of Factor VIII for use in *ex vivo* introduction of genes into cells or tissue intended to be administered to subjects for therapeutic use through a license granted by University of Michigan. The University of Michigan license contains an annual license fee, milestone payments, royalties and sublicense fees as follows:

- (a) an initial license fee of \$25,000 payable to University of Michigan;
- (b) an annual license fee in arrears of \$10,000 rising to \$50,000 following the grant by us of a sublicense or (if sooner) from the sixth anniversary of the license agreement (such annual license fee may be creditable in full against any royalties and/or sublicense fees due during the prior twelve month period on which the annual license fee accrues);
- (c) staged milestone payments of \$750,000 (in aggregate), of which \$400,000 will be creditable against royalties;
- (d) royalties at an initial rate of 5% of net sales, reducing by a percentage point at predetermined thresholds to 2% upon cumulative net sales exceeding \$50 million; and
- (e) sublicense fees at an initial rate of 6% of sublicensing revenues, reducing by a percentage point at predetermined thresholds to 4% upon cumulative sublicensing revenues exceeding \$50 million.

The University of Michigan license expires upon the expiration of the last patent licensed to expire, which is expected to be approximately June 29, 2027.

We are required to use commercially reasonable efforts to bring a product utilizing one or more of the licensed patents to market to commercial use through a commercially reasonable and diligent program and to continue active, diligent efforts during the term of the University of Michigan license. As part of such diligence we are required to achieve specified commercialization and research and development milestones within specified dates. If we fail to achieve any such milestone, we may extend the deadline for such milestone for a period of up to six months for each milestone, subject to payment of \$5,000 per month. If we fail to meet such extended deadline, the University of Michigan may either terminate the license or convert license thereunder to non-exclusive.

The University of Michigan license also requires that we reimburse the University of Michigan for a pro-rated portion (currently 50%) of the costs and expenses of prosecuting the pending patent applications and of maintaining all registered patents licensed to us. If we fail to make the payments due or otherwise breach our obligations under the University of Michigan license, the University of Michigan would have the right to terminate the license and our right to use the patents would end.

Trademarks

Certain names utilized for our products and tools are the subject of trademark applications in certain jurisdictions, though the final choice of name for products and tools has not yet been made and will be subject to marketing considerations and other factors. We have filed applications for BIOPUMP trademark in foreign countries. BIOPUMP is registered in Australia, China, Israel, New Zealand, the European Union, South Korea, Norway and Russia in the framework of an International Trademark Registration as well as in Hong Kong and Mexico. BIOPUMP trademark applications are currently pending in Brazil, India and Canada, as well as in the United States. There can be no assurance that a third party will not oppose any registration, that the respective Trademark Offices will issue a registration certificate or that we will otherwise be successful in perfecting trademark rights for the marks in the United States or in foreign countries, the results of any of which would likely have a material adverse effect on our company. We do not currently have trademark applications in any jurisdiction for EPODURE, INFRADURE, HEMODURE or DermaVac. We had been contacted by a third party regarding the use of that party's Biopump trademark which we believe is inapplicable to our use and registration of the mark BIOPUMP and communicated this to the said third party. We have now received said party's consent to the use and registration of our BIOPUMP trademark in Israel.

Government Regulation

General

The production, distribution, and marketing of products employing our technology, and our development activities, are subject to extensive governmental regulation in the United States and in other countries. In the United States, our products are regulated as biologics and medical devices and are subject to the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations of the FDA, as well as to other federal, state, and local statutes and regulations. These laws, and similar laws outside the United States, govern the clinical and preclinical testing, manufacture, safety, effectiveness, approval, labeling, distribution, sale, import, export, storage, record-keeping, reporting, advertising, and promotion of our products. Product development and approval within this regulatory framework, if successful, will take many years and involve the expenditure of substantial resources. Violations of regulatory requirements at any stage may result in various adverse consequences, including the FDA's and other health authorities' delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions.

The following paragraphs provide further information on certain legal and regulatory issues with a particular potential to affect our operations or future marketing of products employing our technology.

Research, Development, and Product Approval Process in the United States

We believe that the FDA will consider the Biopump Platform Technology a combination product because it combines two regulated components: a medical device and a biological product. The FDA regulatory center that has primary jurisdiction over a combination product is determined by the combination product's "primary mode of action," i.e., the single mode of action that provides the most important therapeutic action. We believe the most important therapeutic action is provided by the biological product(s), which would result in the FDA's Center for Biologics Evaluation and Research (CBER) leading the review of our product, with consultation from the Center for Devices and Radiological Health (CDRH) for the device aspects of the Biopump product. We also believe combination products like the Biopump Platform Technology are likely to be evaluated under a biological license application (BLA) if and when it is submitted for approval, although it is possible that the FDA might require a different approach. At this time, we believe that it is likely the research, development, and approval process for our product is likely to take a path that is usually followed for therapeutic biologicals.

The research, development, and approval process in the United States is intensive and rigorous and generally takes many years to complete. Also, there is no guarantee that a product approval will ultimately be obtained. The typical process required by the FDA before a therapeutic biological may be marketed in the United States includes:

- Preclinical laboratory and animal tests performed, usually in compliance with FDA’s Good Laboratory Practices (GLP) regulations;
- Submissions to the FDA of an IND application, which must become effective before clinical trials may commence in the United States;
- Clinical studies to evaluate the drug’s safety and effectiveness for its intended uses under the IND;
- FDA review of whether the facility in which the product is manufactured, processed, packed, or held meets standards designed to assure the product’s continued quality;
- Submission of a marketing application to the FDA; and
- Approval of the marketing application by the FDA.

During preclinical testing, laboratory studies are performed with the product candidate. Biological testing is typically done in animal models to demonstrate the activity of the compound against the targeted disease or condition and to assess the effects of the new product candidate on various organ systems, as well as its relative therapeutic effectiveness and safety. These studies must generally meet GLP requirements to be considered valid by the FDA.

An IND application must be submitted to the FDA and become effective before studies in humans (i.e., clinical trials) in the United States may commence. The FDA will consider, among other things, the safety of allowing studies proposed under the IND to proceed. Support for the IND can include preclinical study results as well as relevant human experience. Some human experience might be provided from foreign clinical trials that were not conducted under an IND. The FDA will accept as possible support for an IND a well-designed and well-conducted foreign clinical trial if (1) it was conducted in accordance with good clinical practices (GCP), including review and approval (or provision of a favorable opinion) by an independent ethics committee (IEC) before initiating a study, continuing review of an ongoing study by an IEC, and compliance with informed consent principles, and (2) FDA is able to validate the data from the study through an onsite inspection if the agency deems it necessary. In some cases, we may apply for orphan drug status from the FDA and/or EMA in order to secure additional exclusivity and tax benefits.

In the case of products for certain serious or life-threatening diseases, the initial human testing is sometimes done in patients with the disease rather than in healthy volunteers. Because these patients are already afflicted with the target disease or condition, it is possible that such studies will also provide results traditionally obtained in phase II studies. These studies are often referred to as “phase I/IP” studies. However even if patients participate in initial human testing and a phase I/II study is conducted, the sponsor is still responsible for obtaining all the data usually obtained in both phase I and phase II studies.

U.S. law requires that studies conducted to support approval for product marketing be “adequate and well controlled.” Usually this means, among other things, that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control, although other kinds of controls are sometimes used. Studies must also be conducted in compliance with GCP requirements, including informed consent and Institutional Review Board (IRB) requirements. In addition, with certain exceptions, sponsors of clinical trials are required to register clinical trials, and disclose clinical trial information, for posting on the publicly-available clinicaltrials.gov website.

The clinical trial process can potentially take several years to complete. Also, the FDA may prevent clinical trials from beginning or may place clinical trials on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. Trials in the United States involving human subjects are also subject to advance approval and oversight IRBs, which have the authority to request modifications to a clinical trial protocol and to suspend or terminate its approval of a protocol if a clinical trial is not being conducted in accordance with the IRB’s requirements or where there is unexpected serious harm to subjects. Side effects or adverse events that are reported during clinical trials can potentially delay, impede, or prevent continued research and development.

Also, the FDA places certain restrictions on the use of foreign clinical data that are intended to be relied on as the sole basis for approval. A marketing application based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved only if (1) the foreign data are applicable to the U.S. population and U.S. medical practice; (2) the studies have been performed by clinical investigators of recognized competence; and (3) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

Following the completion of the clinical trial program for the product, a Biologic License Application (BLA) must be submitted by the applicant, and approved by the FDA, before commercial marketing of the product may begin in the United States. The BLA must include a substantial amount of data and other information concerning the safety and effectiveness of the product from laboratory, animal, and clinical testing, as well as data and information on manufacturing, product quality and stability, and proposed product labeling. Also, each domestic and foreign manufacturing establishment, including any contract manufacturers, must be listed in the BLA and must be registered with the FDA. The BLA must usually be accompanied by an application fee, although certain deferral, waivers, and reductions may be available, e.g., for a small business submitting its first BLA. For fiscal year 2014, the BLA application fee is \$2,169,100.

There are regulatory mechanisms which might potentially speed up the development and approval process for certain kinds of products. These mechanisms are Fast Track, Accelerated Approval, Priority Review, and Breakthrough status.

- Fast Track is a process designed to facilitate the development, and expedite the review of biological products to treat serious diseases and fill an unmet medical need by providing (1) more frequent meetings with the FDA to discuss product development, (2) more frequent written correspondence from the FDA about such things as the design of the proposed clinical trials, (3) eligibility for Accelerated Approval, and (4) a “rolling review” process, which allows a company to submit sections of its application for review by the FDA, rather than waiting until every section of the application is completed before the entire application can be submitted for review.
- Accelerated Approval allows earlier approval of biological products to treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint, which can potentially reduce the time needed to conduct trials. Where the FDA approves a product on the basis of a surrogate marker, it requires the sponsor to perform post-approval studies as a condition of approval, and may withdraw approval if post-approval studies do not confirm the intended clinical benefit or safety of the product. Special rules would also apply to the submission to the FDA of advertising and promotional materials prior to use.
- Priority Review designation is given to biological products that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes the FDA to review an application is reduced. The goal for completing a Priority Review is six months. Priority Review status can apply both to products that are used to treat serious diseases and to products for less serious illnesses.
- Breakthrough Therapy designation is given to biological products that offer, alone or in combination, a treatment to a serious or life-threatening disorder, and preliminary clinical evidence indicates the drug may demonstrate substantial benefits over existing therapies on statistically significant clinical endpoints. Upon granting the breakthrough therapies designation, the FDA will expedite the development and review of the drug. We will pursue this strategy as appropriate based upon generated Biopump clinical data.

We cannot know for sure whether the FDA would allow us to take advantage of any of these mechanisms in developing our products.

Each BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will “file” the BLA, and perform its substantive review of the application. The FDA can refuse to file a BLA that it deems incomplete or not properly reviewable. An applicant can then either request that the BLA be filed over FDA’s protest, amend the application to address the deficiencies the FDA has alleged and resubmit it, or not pursue the application.

The FDA’s current performance goals for reviewing of BLAs are six months from submission for BLAs that the FDA designates as priority applications and 10 months from submission for standard applications. However, the FDA is not legally required to complete its review within these periods, and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, can often be a “complete response” letter that describes additional work that must be done before the application can be approved. This work can sometimes be substantial. Also, even if the FDA approves a product, it may limit the approved therapeutic uses for the product through indications and usage statements it allows to be approved in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk evaluation and mitigation strategy (REMS), or otherwise limit the scope of any approval. Also, before any approval, facilities that manufacture the product must generally pass an FDA inspection.

Overall research, development, and approval times depend on a number of factors, including the period of review at the FDA, the number of questions posed by the FDA during review, how long it takes to respond to the FDA's questions, the severity or life threatening nature of the disease in question, the availability of alternative treatments, the ability to take advantage of mechanisms that might facilitate development and FDA review of a product, the availability of clinical investigators and eligible patients, the rate of enrollment of patients in clinical trials, and the risks and benefits demonstrated in the clinical trials.

There are additional issues regarding our products that might be important to its research, development, and approval. Manufacturing issues regarding biological products can be particularly complex. Also the Biopump Platform Technology presents a somewhat different situation than those the FDA often deals with (i.e. a situation in which a biological therapeutic is manufactured at one or a few sites). Also, because the product will probably be considered a combination product with a device product component, there are device-related manufacturing and other compliance issues (e.g. cGMPs and adverse event reporting) that might be implicated by the product. These issues may increase the complexity of circumstances we will face with the FDA.

Post-Approval Requirements

Any products for which we receive FDA approvals will be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion, and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Furthermore, product manufacturers must continue to comply with current Good Manufacturing Practices (cGMP) requirements, which are extensive and require considerable time, resources, and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented, and other types of changes to the approved product—such as changes in materials or adding indications or labeling claims—are also subject to further FDA review and approval.

Manufacturers and other entities involved in the manufacturing and distribution of an approved biological or medical device product are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage, and shipment of the product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release. On January 22, 2013, the FDA published final regulations for cGMPs for combination products. The final cGMP requirements for combination products are based upon the premise that constituent parts of a combination product retain their regulatory status after they are combined. In other words, combination products comprised of a biological product and a medical device are required to comply with both cGMPs for biological products and cGMPs for devices.

Manufacturers of biological products must also report to the FDA any deviations from cGMP that may affect the safety, purity, or potency of a distributed product, or any unexpected or unforeseeable event that may affect the safety, purity, or potency of a distributed product. The regulations also require investigation and correction of any deviations from cGMP and impose documentation requirements.

We might rely on third parties for the production of our products. FDA and state inspections may identify compliance issues at the facilities of contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Furthermore, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical studies, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

In addition, from time to time, new legislation is enacted that can significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Orphan Drugs

Under the Orphan Drug Act, Pub. L. No. 97-414 (1983), special incentives exist for companies to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 people in the United States. Companies may request that the FDA grant an orphan drug designation prior to approval. Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, reduced filing fees for marketing applications, and a special seven-year period of market exclusivity after marketing approval. Orphan Drug exclusivity prevents FDA approval of applications by others for the same drug and the designated orphan disease or condition. The FDA may approve a subsequent application from another entity if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. A grant of an orphan designation is not a guarantee that a product will be approved. If a sponsor receives orphan drug exclusivity upon approval, there can be no assurance that the exclusivity will prevent another entity or a similar product from receiving approval for the same or other uses.

To qualify for orphan designation in the European Union, a medicine must meet a number of criteria:

- it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating;
- the prevalence of the condition in the EU must not be more than five in 10,000 people or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and
- no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

Applications for orphan designation are examined by the EMA's Committee for Orphan Medicinal Products (COMP), using the network of experts that the Committee has built up. The evaluation process takes a maximum of 90 days from validation.

Potential Competition with "Biosimilar" Products

The Biologics Price Competition and Innovation Act (BPCIA) was enacted as part of the Patient Protection and Affordable Care Act of 2010 (ACA), Pub. L. No. 111-148 (2010). The BPCIA authorizes the FDA to approve "abbreviated" BLAs for products whose sponsors demonstrate they are "biosimilar" to reference products previously approved under BLAs. The FDA may also separately determine whether "biosimilar" products are "interchangeable" with their reference products. However, the FDA may not approve an "abbreviated" BLA for a biosimilar product until at least twelve years after the date on which the BLA for the reference product was approved. FDA approval could be further delayed if the reference products are subject to unexpired and otherwise valid patents.

Prior to the enactment of the BPCIA, information in approved BLAs could not be relied upon by other manufacturers to establish the safety and efficacy of their products for which they were seeking FDA approval. (In contrast, since at least 1984, pharmaceutical manufacturers have been able to submit Abbreviated New Drug Applications for "generic drugs" that are materially identical to reference drugs approved under New Drug Applications.) Accordingly, if the Biopump Platform Technology were approved under a BLA, other manufacturers potentially could develop and seek FDA approval of "biosimilar" products at some point in the future.

U.S. Fraud and Abuse Laws

Anti-Kickback Statute and HIPAA Criminal Laws

We are subject to various federal and state laws pertaining to health care “fraud and abuse.” The federal Anti-Kickback Statute makes it illegal for any person, including a pharmaceutical, biologic, or medical device company (or a party acting on its behalf), to knowingly and willfully solicit, offer, receive or pay any remuneration, directly or indirectly, in exchange for, or to induce, the referral of business, including the purchase, order or prescription of a particular item or service, or arranging for the purchase, ordering, or prescription of a particular item or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid. In 1996, under the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. No. 104-191 (1996), the Anti-Kickback Statute was expanded to be made applicable to most federal and state-funded health care programs. The definition of “remuneration” has been broadly interpreted to include any item or service of value, including but not limited to gifts, discounts, the furnishing of free supplies or equipment, commercially unreasonable credit arrangements, cash payments, waivers of payments or providing anything at less than its fair market value. Several courts have interpreted the Anti-Kickback Statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of business reimbursable by a federal healthcare program, the statute has been violated. The ACA further amended the federal Anti-Kickback Statute to clarify that “a person need not have actual knowledge of this section or specific intent to commit a violation of this section.” Therefore, all courts are likely to use the “one purpose” test for evaluating intent. Penalties for violations include criminal penalties, civil sanctions and administrative actions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federally-funded healthcare programs. In addition, some kickback allegations have been held to violate the federal False Claims Act, which is discussed in more detail below.

The federal Anti-Kickback Statute is broad and prohibits many arrangements and practices that may be lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous and beneficial arrangements, Congress created several exceptions in the Social Security Act and has authorized the U.S. Department of Health and Human Services (HHS) to publish regulatory “safe harbors” that exempt certain practices from enforcement action under the Anti-Kickback Statute prohibitions. For example, there are safe harbors available for certain discounts to purchasers, personal services arrangements and various other types of arrangements. However, safe harbor protection is only available for transactions that satisfy all of the narrowly defined safe harbor provisions applicable to the particular remunerative relationship. We seek to comply with such safe harbors whenever possible. Conduct and business arrangements that do not strictly comply with all the provisions of an applicable safe harbor, while not necessarily illegal, face an increased risk of scrutiny by government enforcement authorities and an ongoing risk of prosecution.

In addition, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare services reimbursed by any third-party payer, not only the Medicare and Medicaid programs or other governmental payers. At least one state, California, also has adopted a law requiring pharmaceutical companies to implement compliance programs to prevent and deter conduct that may violate fraud and abuse laws that comply with the voluntary industry guidelines and the HHS Office of Inspector General (OIG) compliance guidance. While we believe we have structured our business arrangements to comply with these laws, it is possible that the government could find that such arrangements violate these laws, which could have a material adverse effect on our business, results of operations and financial condition.

HIPAA created two new federal crimes: health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal and state health care programs such as Medicare and Medicaid. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment. Additionally, HIPAA granted expanded enforcement authority to HHS and the U.S. Department of Justice (DOJ) and provided enhanced resources to support the activities and responsibilities of the OIG and DOJ by authorizing large increases in funding for investigating fraud and abuse violations relating to health care delivery and payment.

False Claims Laws

Pursuant to various federal and state false claims laws, the submission of false or fraudulent claims for payment may lead to civil money penalties, criminal fines and imprisonment, and/or exclusion from participation in Medicare, Medicaid and other federally funded health care programs. These false claims statutes include the federal False Claims Act, 12 Stat. 696 (1863), which was significantly expanded in both the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 (2009), and in the ACA. In addition, a number of states have enacted similar laws prohibiting the submission of false or fraudulent claims to a state government.

The federal False Claims Act allows the federal government or private individuals to bring suit alleging that an entity or person knowingly submitted (or caused another person or entity to submit or conspired to submit) a false or fraudulent claim for payment to the federal government or knowingly used (or caused to be used) a false record or statement to obtain payment from the federal government. The federal False Claims Act may also be violated if a person files a false statement in order to reduce, avoid, or conceal an obligation to pay money to the federal government, or engages in conduct that may violate the federal Anti-Kickback Statute. The ACA expressly states that claims arising out of violations of the federal Anti-Kickback Statute are false claims for purposes of the federal False Claims Act. Several pharmaceutical and medical device companies have settled claims based on the federal False Claims Act for conduct involving, among other examples, providing free product to purchasers with the expectation that federally-funded health programs would be billed for the product, or instances in which a manufacturer has marketed its product for unapproved and non-reimbursable purposes or encouraged providers to bill government health care programs for unapproved uses of the product. In addition to False Claims Act cases brought directly by the federal government, individuals who file a lawsuit in the name of the federal government may be able to share in amounts recovered by the government in connection with such suits. Such suits, known as qui tam actions, have increased significantly in recent years and have increased the risk that a health care company will have to defend a false claims action, enter into settlements that may include corporate integrity agreements requiring disclosures to the federal government, pay fines or be excluded from the Medicare and/or Medicaid programs as a result of an investigation arising out of such an action. We are not aware of any false claims actions pending against us. However, no assurance can be given that such actions may not be filed against us in the future, or that any non-compliance with such laws would not have a material adverse effect on our business, results of operations and financial condition.

The foregoing description of laws and regulations affecting health care companies is not meant to be an all-inclusive discussion of aspects of federal and state fraud and abuse laws that may affect our business, results of operations and financial condition. Health care companies operate in a complicated regulatory environment. These or other statutory or regulatory initiatives may affect our revenues or operations. No assurance can be given that our practices, if reviewed, would be found to be in compliance with applicable fraud and abuse laws (including false claims laws and anti-kickback prohibitions), as such laws ultimately may be interpreted, or that any non-compliance with such laws or government investigations of alleged non-compliance with such laws would not have a material adverse effect on our business, results of operations and financial condition.

Other U.S. Regulatory Requirements

In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are subject to regulation by various federal, state, and local authorities in addition to the FDA, including the CMS (formerly the Health Care Financing Administration), other divisions of HHS (e.g., OIG), DOJ and individual United States Attorney offices within DOJ, and state and local governments. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508 (1990), and the Veterans Health Care Act of 1992, Pub. L. No. 102-585 (1992), each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws. In addition, we may be subject to federal and state laws requiring the disclosure of financial arrangements with health care professionals.

Moreover, we may become subject to additional federal, state, and local laws, regulations, and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation, and disposal of human tissue, waste, and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

Foreign Regulatory Requirements

We may be subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, manufacture, product registration and approval, and pharmaceutical sales.

Whether or not FDA approval has been obtained, we must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval.

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

In addition, pharmaceutical products may not be imported into, or manufactured or marketed in, the State of Israel absent drug registration or the appropriate license/approval to import/manufacture for clinical trials use.

Reimbursement and Pricing Controls

Third-party payers (Medicare, Medicaid, private health insurance companies and other organizations) may affect the pricing or relative attractiveness of our product candidates by regulating the level of reimbursement provided to the physicians and clinic utilizing our product candidates or by refusing reimbursement. If reimbursement under these programs, or if the amount of time to secure reimbursement is too long, our ability to market our technology and product candidates may be adversely and materially affected. In international markets, reimbursement by private third-party medical insurance providers, including government insurers and independent providers, varies from country to country. In certain countries, our ability to achieve significant market penetration may depend upon the availability of third-party government reimbursement.

In many of the markets where we or our collaborative partners would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject, by law, to direct price controls and to drug reimbursement programs with varying price control mechanisms. Public and private health care payers control costs and influence drug pricing through a variety of mechanisms, including the setting of reimbursement amounts for drugs and biological products covered by Medicare Part B based on their Average Sales Prices calculated by manufacturers in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2010, Pub. L. No. 108-173 (2003), as amended, through negotiating discounts with the manufacturers, and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Drug manufacturers also may be subject to drug rebate agreements with public or private health care payers in exchange for the manufacturers' products being included on plan formularies.

Payers also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. If a payer concludes that a drug is experimental or investigational, in many cases it will deny coverage on that basis alone. Further, many public and private health care payers limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare coverage for physician-administered oncology drugs, the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66 (1993), with certain exceptions, prohibits Medicare carriers from refusing to cover unapproved uses of an FDA-approved drug if the unapproved use is supported by one or more citations in the American Hospital Formulary Service Drug Information, the American Medical Association Drug Evaluations, or the United States Pharmacopoeia Drug Information. Another commonly cited compendium, for example under Medicaid, is the DRUGDEX Information System.

Employees

We currently employ 36 full-time and two part-time employees. None of our employees is represented by a labor union and we have not experienced any strikes or work stoppages. While none of our employees is party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees in Israel by order of the Israel Ministry of Labor. Such orders are part of the employment related laws and regulations which apply to our employees in Israel and set certain mandatory terms of employment. Such mandatory terms of employment primarily concern the length of the workday, minimum daily wages, pension plan benefits for all employees, insurance for work-related accidents, procedures for dismissal of employees, severance pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums. We believe our relations with our employees are good.

Additional Information

Our principal executive offices are located at 435 Devon Park Drive, Building 700, Wayne, Pennsylvania 19087. We conduct our research and development activities primarily from our Israeli location in Misgav Business Park, Misgav. Our telephone numbers are (610) 254-4201 in the United States and +972-4-902-8900 in Israel.

Our website address is www.medgenics.com. The information on or accessible through our website is not part of this Annual Report on Form 10-K. Copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to such reports are available without charge on our website or upon request to us. In addition, our Code of Business Conduct and Ethics, Audit Committee Charter, Compensation Committee Charter and Nominating and Corporate Governance Committee Charter are all available without charge on our website or upon request to us. All such requests should be sent to Medgenics, Inc., Corporate Secretary, 435 Devon Park Drive, Building 700, Wayne, Pennsylvania 19087, or by email request from our website at www.medgenics.com. Amendments to, or waivers from, our Code of Business Conduct and Ethics that apply to our executive officers will be posted to our website. We also post or otherwise make available on our website from time to time other information that may be of interest to our investors.

ITEM 1A - Risk Factors.

Business-Related Risks

We are a clinical stage medical technology company and have a history of significant and continued operating losses and a substantial accumulated earnings deficit and we may continue to incur significant losses.

We are a clinical stage medical technology company and since our inception have been focused on research and development and have not generated any substantial revenues. We have incurred net losses of approximately \$17.13 million, \$15.07 million and \$8.10 million for the years ended December 31, 2013, 2012 and 2011, respectively, and approximately \$82.13 million for the period from inception through December 31, 2013. At December 31, 2013, we had an accumulated deficit of approximately \$81.71 million. We expect to incur additional operating losses, as well as negative cash flow from operations, for the foreseeable future, as we continue to expand our research and development and commence commercialization of our potential product candidates. Our ability to generate revenues from sales of our potential products will depend on:

- successful completion of necessary medical trials which have not advanced beyond phase I/II stage;
- regulatory approval;
- commercialization (through partnership or licensing deals or through internal development) and market acceptance of new technologies and product candidates under development;
- medical community awareness; and
- changes in regulation or regulatory policy.

We believe that initial commercialization of any of our product candidates by us or any future strategic partners is not likely before 2017 and could easily take four years or more.

We will need substantial additional capital for the continued development of our product candidates and for our long-term operations.

As of December 31, 2013, our cash and cash equivalents were approximately \$22.39 million. We believe our existing cash and cash equivalents should be sufficient to meet our operating and capital requirements through the second quarter of 2015. However, changes in our business, whether or not initiated by us, may affect the rate at which we deplete our cash and cash equivalents. Our present and future capital requirements depend on many factors, including:

- the level of patient recruitment in the human EPODURE trial in Israel using the new viral vector and implantation technique, and the clinical result of the study's patients;
- the level of research and development investment required to develop our first orphan and rare disease product candidates, and to maintain and improve the Biopump Platform Technology;
- changes in product development plans needed to address any difficulties that may arise in manufacturing, preclinical activities, clinical studies or commercialization;
- our ability and willingness to enter into new agreements with strategic partners, and the terms of these agreements;
- our success rate in preclinical and clinical efforts;
- costs of recruiting and retaining qualified personnel;
- time and costs involved in obtaining regulatory approvals; and
- costs of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights.

We will require significant amounts of additional capital in the future, and such capital may not be available when we need it on terms that we find favorable, if at all. We may seek to raise these funds through public or private equity offerings, debt financings, credit facilities, or partnering or other corporate collaborations and licensing arrangements. If adequate funds are not available or are not available on acceptable terms, our ability to fund our operations, take advantage of opportunities, develop products and technologies, and otherwise respond to competitive pressures could be significantly delayed or limited, and we may need to downsize or halt our operations.

We have significant severance liabilities and may not be able to satisfy such obligations.

Our balance sheet as of December 31, 2013 includes a net liability of approximately \$0.79 million representing severance payments required under Israeli law and contractual obligations in excess of severance covered by our current insurance policies that would be due if our employees left under circumstances that triggered payment of severance.

Our liability for severance pay is calculated pursuant to the Israeli severance pay law based on the most recent salary for the employees multiplied by the number of years of employment, as of the balance sheet date. Under law, employees are entitled to one month salary (based on the average of the employee's last three months' salary) for each year of employment or a portion thereof. Accordingly, our unfunded severance liability increases upon any increase in an employee's salary. In addition, several employees are entitled to additional severance compensation in accordance with the terms of their respective employment agreements. Our liability for all of our employees is fully provided by an accrual and is mainly funded by monthly deposits with insurance policies. The value of these policies is recorded as an asset in our balance sheet. Our net liability for severance payments is due to additional months of severance provided under our agreements with certain employees and to any shortfall in our deposited amounts caused by increases in salary.

The deposited funds may be withdrawn only upon the fulfillment of the obligation pursuant to Israeli severance pay law or labor agreements. The value of the deposited funds is based on the cash surrender value of these policies and includes profits or losses as appropriate.

We are still in the process of clinical trials and do not have a commercialized product and may never be able to commercialize our product candidates.

We have completed a human clinical trial with respect to our EPODURE Biopump in pre-dialysis patients and are planning to conduct an additional trial in dialysis patients in Israel with a new viral vector and implantation technique. Only a small number of research and development programs ultimately result in commercially successful drugs and drug delivery systems. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons, including:

- failure to obtain approvals for clinical trials;
- lack of familiarity of health care providers and patients;
- low market acceptance as a result of lower demonstrated clinical safety or efficacy compared to other products or other potential disadvantages relative to alternative treatment methods;
- inability to obtain favorable coverage determinations from health plans and third-party payers;
- insufficient or unfavorable levels of reimbursement from government or third-party payers;
- infringement on proprietary rights of others for which we (or our licensees, if any) have not received licenses;
- incompatibility with other therapeutic products;
- potential advantages of alternative treatment methods;
- ineffective marketing and distribution support;
- lack of cost-effectiveness; or
- timing of market introduction of competitive products.

If any of these potential problems occurs, we may never successfully commercialize our Biopump Platform Technology. If we are unable to develop commercially viable products, our business, results of operations and financial condition will be materially and adversely affected.

Our Biopump Platform Technology is still being developed and has not been tested on a large patient population, and, therefore, we do not know all of the possible side effects and may not be able to commercialize our technology as planned.

The Biopump Platform Technology has not been tested on a large number of patients, and is still in an early stage of development. Although we and our advisors believe that the results in patients treated to date have demonstrated POC and shown safety and efficacy of our technology so far in its first application, and although we are encouraged by the FDA clearance to proceed with a human clinical trial in anemia study with EPODURE in dialysis patients, this does not constitute confirmation or approval of the safety and efficacy of our technology, nor have we received such confirmation from any regulatory authority. To date, although we have produced thousands of Biopumps in the laboratory, we have administered Biopumps to only a relatively small number of patients. We are in the early stages of developing the most efficient and effective methods to implant Biopumps so as to attain sustained performance once in the patient and thereby produce the desired therapeutic effect for extended periods of time. While we have attained a number of positive results in our first clinical application, there is significant variability between patients. These and other aspects of the implementation and use of the Biopump Platform Technology are not yet fully developed or proven, and disappointing results and problems could delay or prevent their completion. We are planning on conducting a human trial in Israel using a new viral vector and implantation techniques, which to date have not been tested in humans. Even if the Biopump Platform Technology works well in one indication, it could have disappointing results in others. If so, the development could be stalled or even blocked in one or more indications. Potential risks associated with the use of the Biopump Platform Technology are the development of an immune response to the vector or the encoded protein product, local inflammatory response to the implanted tissue or associated with the insertion of the Biopump in the surrounding tissue, autoimmunity to the endogenous protein product or potential overdose of protein due to difficulties in managing the continuous supply in the patient in accordance with patient need. Risk for immunogenic reaction to the vector is based on clinical studies using first generation adenoviral vectors that contain a full complement of viral proteins. We currently use a gutless adenoviral vector in all our development activities and our current trial to eliminate the risk of immune rejection of the Biopumps prepared with viral vector particles. While these gutless adenoviral vectors do not include genes for viral proteins, the risk for somehow re-establishing expression of viral proteins cannot be entirely ruled out.

The basis for the risks described above is currently only theoretical since these effects have not been seen in the small number of patients that have received a Biopump in our EPODURE clinical trials or in preclinical safety studies performed in mice. However, the possible side effects and full efficacy and safety of the technology need to be tested in a substantial number of patients to verify this. Our previous safety tests may not be representative of either a larger multi-centric test or the commercial version of the technology in the general population. In addition, the full impact of the technology, and its many possible variations, on the body is, as yet, unknown. Although no side effects attributed to the Biopump Platform Technology were found to date in our EPODURE clinical trials, other than minor bruising at the implantation site, the possibility cannot be ruled out that serious side effects might be borne out by further trials, and if so, this could have serious implications on the viability of the technology and our business.

Although the Biopump Platform Technology aims to minimize the residual number of viral vector particles and their proteins introduced into a body, there is a chance that the cumulative effect of Biopump reimplantation could result in an eventual buildup of viral proteins and an immunogenic reaction against the Biopumps preventing further implantations, a scenario which could call the viability of the technology into question.

Severe side effects or complications in trials, or post-approval, could also result in financial claims and losses against us, damage our reputation, and increase our expenses and reduce our assets. In addition, our product candidates may not gain commercial acceptance or ever be commercialized.

We are currently completely dependent upon the successful development of our Biopump Platform Technology. If we fail to successfully complete its development and commercialization or enter into licensing or partnership agreements, we will not generate operating revenues.

All of our efforts are currently focused on the development of our Biopump Platform Technology. There is no guarantee that we will succeed in developing products based on our Biopump Platform Technology. If we or any partner(s) or collaborator(s) that we may enter into a relationship with are unable to consummate the production of Biopumps to provide the sustained protein therapy to treat various chronic diseases in a safe, stable, commercial end-product form, we will be unable to generate any revenues. There is no certainty as to our success, whether within a given time frame or at all. Any delays in our schedule for clinical trials, regulatory approvals or other stages in the development of our technology are likely to cause us additional expense, and may even prevent the successful finalization of any or all of our product candidates. Delays in the timing for development of our technology may also have a material adverse effect on our business, financial condition and results of operations due to the possible absence of financing sources for our operations during such additional periods of time. Although we may pursue other technologies (either developed in-house or acquired), there is no assurance that any other technology will be successfully identified or exploited.

Clinical trials involve lengthy and expensive processes with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials, which would cause us or regulatory authorities to delay or suspend clinical trials, or delay the analysis of data from completed or ongoing clinical trials. We estimate that clinical trials involving various applications of our Biopump Platform Technology will continue for several years; however, such trials may also take significantly longer to complete and may cost more money than we expect. Failure can occur at any stage of testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of the current, or a future, more advanced, version of our Biopump Platform Technology, including but not limited to:

- delays in obtaining regulatory approvals to commence a clinical trial;
- failure or inability to recruit qualified investigators;
- slower than anticipated patient recruitment and enrollment;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;

- an inability to monitor patients adequately during or after treatment; and
- problems with investigator or patient compliance with the trial protocols.

A number of companies in the medical device, biotechnology, and biopharmaceutical industries including those with greater resources and experience than us have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. Despite the successful results reported in early clinical trials regarding our EPODURE Biopump, we do not know whether any clinical trials we or any future clinical partners may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market EPODURE or any other product based on our Biopump Platform Technology. If later-stage clinical trials involving our Biopump Platform Technology do not produce favorable results, our ability to obtain regulatory approval may be adversely impacted, which will have an adverse material effect on our business, financial condition and the results of our operations.

Potential difficulty with, and delays in, recruiting additional patients for human clinical trials may adversely affect the timing of our clinical trials and our working capital requirements.

Our research and development is highly dependent on timely recruitment of the requisite number and type of patients for our clinical trials. We have previously found it very difficult to recruit such patients and the increased volume and ethnic backgrounds required for future testing may render such testing even more difficult. Such larger studies will likely be based on the use of multicenter, multinational design, which can prove difficult to manage and could result in delays in patient recruitment. In addition, as we pursue development of the Biopump in orphan and rare disease applications, we may find it difficult to find sufficient treatment-naïve patients needed for initial trials, especially within commercially-reasonable geographical regions. Delays in the recruitment of such patients could delay our trials and negatively impact our working capital requirements.

Potential difficulty or delay in obtaining sufficient research and development facilities may adversely affect the timing of our clinical trials, the further development of our technology and our working capital requirements.

With the recent change in strategy toward rare and orphan diseases, we have significantly expanded our list of research targets which has necessitated an increase in laboratory space and additional equipment. Although we have a plan to enlarge our existing laboratory space in Israel without significant disruption to the current research and development operations, construction delays, unforeseen delays in acquiring equipment, or other unforeseen problems could delay our current research and development plan and timing. Potential difficulty with and delays in construction for expanding our laboratory space in Israel may adversely affect the timing of our research, clinical trials and further development of our technology. Unforeseen cost overruns or other unforeseen expenses related to the expansion of our research and development facilities could negatively impact our working capital requirements.

Potential difficulty with, and delays in, obtaining vectors necessary for conducting human clinical trials and additional research and development of the Biopump Platform Technology may adversely affect the timing of our clinical trials, the further development of our technology and our working capital requirements.

We need specific vectors in order to conduct our research and development of our Biopump Platform Technology and to create Biopumps to conduct our clinical trials. We currently use only one outside source for the production and delivery of research grade versions of new vectors for developing new products and have begun to develop the production of the necessary vectors internally. Such outside source is highly dependent on the work of a particular individual. Although we have a contract with such source, there is a possibility that the source could discontinue its business or the contract could be terminated, that the particular individual could become unable to work on the production of vectors or that other problems could occur with the timely production and delivery of vectors. We will continue our internal program to make viral vectors as a hedge against a loss of our current source. If we are unable to obtain or produce internally the necessary vectors, our research and development of rare and orphan disease targets will be severely delayed. Vectors intended for use in clinical trials must be produced by other vector suppliers who manufacture according to strict requirements of Good Manufacturing Practice (GMP). We have worked with one such GMP vector manufacturer who has supplied the GMP vectors used in our EPODURE human clinical studies and we intend to continue to order new GMP vectors when needed from such supplier. There is a possibility that the source would discontinue its business or that other problems could occur with the timely production and delivery of GMP vectors. If this were to occur, we would need to establish GMP vector production at one or more alternative GMP vector manufacturers. Delays in obtaining the vectors could delay any new trials. Without the necessary vectors, we would be unable to continue the research and development of our technology, which would negatively impact our working capital requirements.

We may not successfully establish and maintain relationships with third-party service providers and collaborators, which could adversely affect our ability to develop our EPODURE product candidate.

Our ability to commercialize our EPODURE technology is dependent on our ability to reach strategic licensing and other development agreements with appropriate partners, including pharmaceutical companies and biotech firms. If we are unable to successfully negotiate such agreements, we may not be able to continue to develop the EPODURE product without raising significant additional capital for commercialization.

The successful adoption of Biopump Platform Technology also relies on our ability to bring about practical, reliable and cost-effective production of Biopumps on a commercial scale and its use in patients in widespread locations. This requires the design, development and commercial scale-up of Biopump manufacturing capability, intended for implementation in regional Biopump processing centers, together with appropriate logistical capabilities to enable local treatment of patients in their communities, in a cost effective and reliable manner. Biopump processing is intended to be effected using semi-automated processing stations employing sealed cassettes and other single use items for each patient. Although we have experienced initial positive results in processing MOs in individual closed processing chambers that were shipped from Israel at our contract manufacturing organization (CMO) in a GMP-certified facility in California, we or our CMO may not necessarily be able to replicate those results or be able to accommodate greater amounts. Treatment of patients in various locations is dependent upon reliable acquisition of MOs and implantation or ablation of Biopumps by trained local physicians, using appropriate proprietary and nonproprietary devices and products, and upon the transport of micro-organs and Biopumps between the Biopump processing centers and local treatment clinics via reliable and cost effective logistical arrangements. It may also be important that the processing center not require highly skilled operators, specialist laboratories or clean rooms. The inability to adequately scale and rollout such technology could damage the cost-effectiveness and therefore one of the anticipated competitive advantages of the Biopump Platform Technology.

Our core business strategy is to develop the Biopump for use in rare and orphan disease markets that our company would internally develop and launch. However, we do plan to enter into collaborative relationships or strategic partnerships and/or license the EPODURE program after receipt of POC results utilizing the new viral vector and implantation protocol. We may not be able to identify such collaborators and partners on a timely basis and we may not be able to enter into relationships with any future collaborator(s) or partner(s) on terms that are commercially beneficial to us or at all. In addition, such relationships and partnerships may not come to fruition or may not be successful. Our agreements with these third parties may also contain provisions that restrict our ability to develop and test our product candidates or that give third parties rights to control aspects of our product development and clinical programs.

The third-party contractors may not assign as great of a priority to our clinical development programs or pursue them as diligently as we would if we were undertaking such programs directly and, accordingly, may not complete activities on schedule, or may not conduct the studies or our clinical trials in accordance with regulatory requirements or with our trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if their performance is substandard, we may be required to replace them.

In addition, conflicts may arise with our collaborators, e.g. those concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any conflicts arise with our existing or future collaborators, they may act in their self-interest, which may be adverse to our best interests. The third-party contractors may also have relationships with other commercial entities, some of whom may compete with us. If the third-party contractors work with our competitors, our competitive position may be harmed.

In addition, although we attempt to audit and control the quality of third-party data, we cannot guarantee the authenticity or accuracy of such data, nor can we be certain that such data has not been fraudulently generated. The failure of third parties to carry out their obligations towards us would materially adversely affect our ability to develop and market our Biopump Platform Technology. To date, we have only entered into one collaboration agreement which addressed the feasibility and laboratory development of the HEMODURE Biopump. That agreement expired in September 2011.

While our new strategic focus is on rare and orphan diseases, therapeutic proteins and peptides for these diseases have never been produced by the Biopump, and we may not be successful in creating a Biopump that produces proteins and peptides for the treatment of rare and orphan diseases.

While the Biopump's attributes of producing low levels of autologous proteins for an extended period of time would appear to be highly amenable to treating rare and orphan diseases, we have not yet created a Biopump that addresses a rare or orphan disease and may never overcome the technical hurdles. In addition, we may target rare and orphan diseases that require peptides or proteins with post-translational modifications for efficacy, and we have not yet produced peptides or proteins with post-translational modifications in the Biopump. The production of peptides and/or proteins with post-translational modifications could require us to develop new techniques of protein production from the Biopump which may delay research and development timelines or may be simply too great to overcome.

We have no marketing experience, sales force or distribution capabilities. If our product candidates are approved, and we are unable to recruit key personnel to perform these functions, we may not be able to successfully commercialize the products.

Although we do not currently have any marketable products, our ability to produce revenues ultimately depends on our ability to sell our product candidates if and when they are approved by the FDA and other regulatory authorities. We currently do not have a marketing and sales staff or distribution capabilities. Developing a marketing and sales force is also time-consuming and could delay the launch of new products or expansion of existing product sales. In addition, we will compete with many companies that currently have extensive and well-funded marketing and sales operations. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, our ability to generate revenues will suffer.

Furthermore, even if we enter into marketing and distributing arrangements with third parties, these third parties may not be successful or effective in selling and marketing our Biopump Platform Technology. If we fail to create successful and effective marketing and distribution channels, our ability to generate revenue and achieve our anticipated growth could be adversely affected. If these distributors experience financial or other difficulties, sales of our products could be reduced, and our business, financial condition and results of operations could be harmed.

We are subject to intense government regulation and we may not be able to successfully complete the necessary clinical trials.

Approval for clinical trials depends, among other things, on data obtained from our pre-clinical and clinical activities, including completion of pre-clinical animal and in vitro studies in a timely manner. These pre-clinical and clinical activities must meet stringent quality assurance and compliance requirements. Data obtained from such activities are susceptible to varying interpretations, which could delay, limit or prevent regulatory approvals. Approval also depends on our obtaining certain key materials such as the GMP produced gutless adenoviral vector, which is prepared through a contract with a GMP vector manufacturer. Being a new version of an adenoviral vector, production of gutless adenoviral vector involves the use of certain special techniques for its preparation, which are somewhat different from those normally used by GMP vector manufacturers of first generation adenoviral vectors and such manufacturer may not be able to meet our requirements on a timely basis, or at all. Delays in obtaining a GMP vector needed for a specific clinical trial could delay the start of the trial. In addition, we cannot guarantee approval of our clinical trial protocols under the human subject protection laws and regulations of the countries where such trials are planned.

We currently have limited experience in and resources for conducting the large-scale clinical trials which may hamper our ability to obtain or comply with regulatory approval. The failure to comply with applicable regulatory requirements may result in criminal prosecution, civil penalties, product recalls, withdrawal of product approval, mandatory restrictions and other actions, which could impair our ability to conduct business.

The FDA and other health authorities will regulate our product candidates and we may never receive regulatory approval to market and sell our product candidates.

Our product candidates will require regulatory approvals prior to sale. In particular, our product candidates are subject to stringent approval processes, prior to commercial marketing, by the FDA and by comparable agencies in all countries where we operate and desire to introduce our product candidates, whether sold via a strategic partner or directly by us. These requirements range from vector and Biopump efficacy and safety assessment in phase III clinical trials to long-term follow-up assessments on treated patients in clinical trials for product approval for sale. The process of obtaining FDA and corresponding foreign approvals is costly and time-consuming, and we cannot assure that such approvals will be granted. Also, the regulations we are subject to change frequently and such changes could cause delays in the development of our product candidates.

It typically takes a company several years or longer to satisfy the substantial requirements imposed by the FDA and comparable agencies in other countries for the introduction of therapeutic pharmaceutical and biological products. Pharmaceutical or biological products must be registered in accordance with applicable law before they can be manufactured, marketed and distributed. This registration must include medical data proving the product's safety, efficacy and clinical testing. Also included in product registration should be references to medical publications and information about the production methods and quality control.

To obtain regulatory approvals in the United States, we or a collaborator must ultimately demonstrate to the satisfaction of the FDA that our product candidates are sufficiently safe and effective for their proposed administration to humans. Many factors, both known and unknown, can adversely impact clinical trials and the ability to evaluate a product candidate's safety and efficacy, including:

- FDA or other health regulatory authorities or instructional review boards (e.g., IRB) decision(s) not to approve a clinical trial protocol or place a clinical trial on hold;
- suitable patients not enrolling in a clinical trial in sufficient numbers or at the expected rate, for reasons such as the size of the prospective patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the perceptions of investigators and patients regarding safety, and the availability of other treatment options;
- clinical trial data being adversely affected by trial conduct or patient withdrawal prior to completion of the trial;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians;
- patients experience serious adverse events, including adverse side effects of our drug candidates, for a variety of reasons that may or may not be related to our product candidates, including the advanced stage of their disease and other medical problems;
- patients in the placebo or untreated control group exhibiting greater than expected improvements or fewer than expected adverse events;
- third-party clinical investigators not performing the clinical trials on the anticipated schedule or consistently with the clinical trial protocol and good clinical practices, or other third-party organizations not performing data collection and analysis in a timely or accurate manner;
- service providers, collaborators or co-sponsors not adequately performing their obligations in relation to the clinical trial or cause the trial to be delayed or terminated;
- being unable to obtain a sufficient supply of manufactured clinical trial materials;
- regulatory inspections of manufacturing facilities requiring us or a co-sponsor to undertake corrective action or suspend the clinical trials;
- interim results of the clinical trial being inconclusive or negative;
- clinical trial, although approved and completed, generating data that are not considered by the FDA or others to be sufficient to demonstrate safety and efficacy; and
- changes in governmental regulations or administrative actions affecting the conduct of the clinical trial or the interpretation of its results.

There can be no assurance that our clinical trials will in fact demonstrate, to the satisfaction of the FDA and others, that our product candidates are sufficiently safe or effective. The FDA or we may also restrict or suspend our clinical trials at any time if either believes that we are exposing the subjects participating in the trials to unacceptable health risks.

Delays in obtaining such clearances and/or changes in existing requirements could have a material adverse effect on our company by making it difficult to advance product candidates or by reducing or eliminating their potential or perceived value and, therefore, our ability to conduct our business as currently planned could materially suffer. Failure to obtain required regulatory approvals could require us to delay, curtail or cease our operations. Even if we invest the necessary time, money and resources required to advance through the FDA approval process, there is no guarantee that we will receive FDA approval of our product candidates.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repairs, replacements, refunds, recalls, or seizures of our products;
- operating restrictions, partial suspension, or total shutdown of production;
- refusing our requests for regulatory clearance or premarket approval of new products, new intended uses, or modifications to existing products;
- withdrawing regulatory clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, it could adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approvals, our products will be subject to ongoing regulatory review and if we fail to comply with continuing regulations, we could lose those approvals and our business, financial condition and results of operations would be seriously harmed.

Even if our Biopump Technology Platform receives initial regulatory approval or clearance for specific therapeutic applications, we will still be subject to ongoing reporting obligations, and such product and the related manufacturing operations will be subject to continuing regulatory review, including FDA inspections. This ongoing review may result in the withdrawal of our product from the market, the interruption of manufacturing operations and/or the imposition of labeling and/or marketing limitations related to specific applications of our product. Since many more patients will be exposed to our Biopump Technology Platform following its marketing approval, serious but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of such product. In addition, the manufacturer(s) and the manufacturing facilities that we will use to produce our Biopumps will be subject to periodic review and inspection by the FDA and other similar foreign regulators. Late discovery of previously unknown problems with any product, manufacturer or manufacturing process, or failure to comply with regulatory requirements, may result in actions, such as:

- restrictions on such product, manufacturer or manufacturing process;
- warning letters from the FDA or other regulatory authorities;
- withdrawal of the product from the market;
- suspension or withdrawal of regulatory approvals;
- refusal by such regulator to approve pending applications or supplements to approved applications that we or our licensees (if any) submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our product;
- product seizures or detentions;

- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

In addition, from time to time, legislation is drafted and introduced in the United States that could significantly change the statutory provisions governing any regulatory clearance or approval that we receive from the U.S. regulatory authorities. FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our product. We cannot predict what these changes will be, how or when they will occur or what effect they will have on the regulation of our product. If we, or our licensees, suppliers, collaborative research partners or clinical investigators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we may lose marketing approval for any of the therapeutic applications of our product (to the extent that such applications are initially approved), resulting in decreased or lost revenue from milestones, product rental or usage fees, or royalties.

Even if approved by the necessary regulatory authorities, our product candidates may not gain market acceptance.

The development of a market for new technology is affected by numerous factors, many of which are beyond our control. There can be no assurance the Biopump Platform Technology will gain acceptance within the markets at which it is targeted. Further, the internal structure for medical service provision varies considerably from territory to territory throughout the world and may be, in some cases, subject to public sector procurement processes, which could delay penetration of this market by our product candidates. If the market does not accept our product candidates, when and if we are able to commercialize them, then we may never become profitable. Factors that could delay, inhibit or prevent market acceptance of our product candidates may include:

- timing and receipt of marketing approvals;
- safety and efficacy of the products;
- emergence of equivalent or superior products;
- cost-effectiveness of products;
- findings by health plans or third-party payers that the product candidates are not reasonable and necessary, or are subject to additional prerequisites for coverage;
- decisions by health plans not to cover the Biopump Platform Technology if they conclude that it is experimental or investigational; and
- ineffective marketing.

Our success is first and foremost reliant upon there being a demand for our technology by patients, payers, and in the case of EPODURE, potential strategic partners. We and potential partners will need to establish and manage reliable and cost effective Biopump production capabilities on a large scale. There is risk that such facilities may not be successfully established, may not meet their performance requirements or cost targets, or in other ways fail to deliver the requisite level of reliable and cost-effective Biopumps for clinical use. In addition, sales will rely upon demand for Biopump products, which in turn is dependent upon patient and doctor and other medical practitioner perceptions as to safety, reliability and efficacy of our product candidates. Although our product candidates will be subject to extensive testing, there can be no assurance that consumers will ultimately accept them relating to safety.

Our efforts to comply with federal and state fraud and abuse laws could be costly, and, if we are unable to fully comply with such laws, we could face substantial penalties.

We are subject to extensive federal and state healthcare fraud and abuse laws and regulations, including, but not limited to, the following:

- federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs, such as Medicare and Medicaid;

- federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which creates federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program and which also imposes certain obligations on entities with respect to the privacy, security and transmission of individually identifiable health information;
- federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- federal Foreign Corrupt Practices Act (FCPA), which prohibits, among other things, making payments to foreign officials of any country outside of the United States for the purpose of obtaining or retaining business; and
- state laws analogous to each of the above federal laws, such as state anti-kickback and false claims laws (some of which may apply to healthcare items or services reimbursed by any third-party payer, including commercial insurers), as well as certain state laws that require pharmaceutical and medical device companies to comply with industry voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

If our past or present operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from third-party payer programs such as Medicare and Medicaid and/or the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we may do business are found to be non-compliant with applicable laws, they may be subject to criminal, civil or administrative sanctions including exclusions from government-funded health care programs, which could also negatively impact our operations. Our ongoing efforts to comply with these laws may be costly, and our failure to comply with these laws could have a material adverse effect on our business, financial condition and results of operations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

If any of our key employees discontinue his or her services with us, our efforts to develop our business may be delayed.

Our success will depend on the retention of our directors and other current and future members of our management and technical team, including Michael F. Cola, our President and Chief Executive Officer, John H. Leaman, our Chief Financial Officer, and Garry A. Neil, our Global Head of Research and Development, and on our ability to continue to attract and retain highly skilled and qualified personnel. There can be no assurance that we will retain the services of any of our directors, officers or employees, or attract or retain additional senior managers or skilled employees. Furthermore, we do not carry key man insurance with respect to any of such individuals.

The Biopump Platform Technology is still in development and is dependent on further development and testing to reach commercial production. We currently employ a small number of key personnel including top managers, scientists, engineers and clinical experts who are important to developing the Biopump Platform Technology and have a high level of accumulated knowledge which would be lost if they left our company. If these employees leave our company or otherwise are unable to provide services, there could be significant implications on the timing and cost of future development of the technology. Because competition for qualified personnel in our industry is intense, we may be unable to timely find suitable replacements with the necessary scientific expertise. We cannot assure you that our efforts to attract or retain such personnel will be successful.

If we are not able to obtain and maintain adequate patent protection for our product candidates, we may be unable to prevent our competitors from using our technology

Our ability to commercialize the Biopump Platform Technology, or our product candidates, will depend, in part, on our ability, both in the United States and in other countries, to obtain patents, enforce those patents, preserve trade secrets and operate without infringing the proprietary rights of third parties. Our owned and licensed patent portfolio directed to the Biopump Platform Technology contains 49 issued patents and 58 pending U.S. and international patent applications. We may not successfully obtain patents in the other countries in which patent applications have been or will be filed, and we may not develop other patentable products or processes. In addition, any future patents may not prevent other persons or companies from developing similar or medically equivalent products and other persons or companies may be issued patents that may prevent the sale of our products or that will require us to license or pay significant fees or royalties. Furthermore, issued patents may not be valid or enforceable, or be able to provide our company with meaningful protection. Patent litigation is costly and time-consuming and there can be no assurance that we will have, or will be able to devote, sufficient resources to pursue such litigation. In addition, potentially unfavorable outcomes in such proceedings could limit our intellectual property rights and activities.

We cannot be certain that any of our patent applications, or those of our licensors, will result in issued patents. In addition, because the patent positions of biopharmaceutical companies are highly uncertain and involve complex legal and factual questions, the patents we own and license, or any further patents we may own or license, may not prevent other companies from developing similar or therapeutically equivalent products. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. We cannot be assured that our patents will not be challenged by third parties or that we will be successful in any defense we undertake. Failure to successfully defend a patent challenge could materially and adversely affect our business.

In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent defense and enforcement.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and confidentiality agreements and our employees to execute assignment of invention agreements to us on commencement of their employment. Agreements with our employees also prevent them from bringing any proprietary rights of third parties to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials. However, if our employees, consultants, contractors, outside scientific collaborators or other advisors breach their confidentiality or other obligations to us, we may not be able to successfully or effectively prevent such breach and we could be adversely impacted if the protection of our trade secrets or other intellectual property is compromised.

Even if our product candidates and the methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Our and our licensors' ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions.

Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensors, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited.

Unauthorized parties may try to copy aspects of our product candidates and technologies or obtain and use information we consider proprietary. Policing the unauthorized use of our proprietary rights is difficult. We cannot guarantee that no harm or threat will be made to our or our collaborators' intellectual property. In addition, changes in, or different interpretations of, patent laws in the United States and other countries may also adversely affect the scope of our patent protection and our competitive situation.

There is certain subject matter that is patentable in the United States but not generally patentable outside of the United States. Differences in what constitutes patentable subject matter in various countries may limit the protection we can obtain outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States. These and other issues may prevent us from obtaining patent protection outside of the United States, which would have a material adverse effect on our business, financial condition and results of operations.

As we develop the Biopump Platform Technology, we may need to obtain licenses to use certain patents depending on the specific gene products, proteins, vectors and promoters used in conjunction with the Biopump Platform Technology. These licenses include, for example, one or more specific proteins and promoters used in conjunction with certain genes to control their expression. There is no assurance that we will obtain licenses for such technology or would be able to obtain licenses to any third party intellectual property on commercially reasonable terms.

Additionally, there can be no assurance that we can successfully develop non-infringing alternatives on a timely basis, or license non-infringing alternatives, if any exist, on commercially reasonable terms. A significant intellectual property impediment to our ability to develop and commercialize our product candidates could adversely affect our business prospects.

Even if patents are issued to us or our licensors regarding our product candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid or unenforceable, lack of utility, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents.

We cannot assure you that third parties cannot and will not design around our patents and develop similar products or that we will be successful in enforcing our patents on such design around products. The biosimilars pathway created under the Biologics Price Competition and Innovation Act (BPCIA) may allow for another manufacturer to develop a non-patent infringing product using data from our own clinical trials. Prior to the enactment of BPCIA, information in approved Biologic License Applications (BLAs) could not be relied upon by other manufacturers to establish the safety and efficacy of their products for which they were seeking FDA approval. Accordingly, if the Biopump Platform Technology were approved under a BLA, other manufacturers potentially could develop and seek FDA approval of "biosimilar" products at some point in the future.

We are heavily reliant on licenses from third parties and any loss of these rights would adversely affect our business.

We do not own some of the patents upon which the Biopump Platform Technology is based. We license such patents exclusively from Yissum Research Development Company of the Hebrew University of Jerusalem (Yissum), subject to certain specific reservations and restrictions. We have certain monetary and operational obligations under the license agreement with Yissum. If we fail to perform any of our obligations under the Yissum license agreement, Yissum may have the right to declare a breach of the Yissum license agreement. Upon such a breach, the Yissum license agreement could be terminated and the intellectual property could revert to Yissum and we may be unable to use or further develop the Biopump Platform Technology in those circumstances.

We have also obtained a non-exclusive license to technology from Baylor College of Medicine (BCM), Houston, Texas. The license is subject to certain specific reservations and restrictions including BCM's required approval for the sale, market, transfer, sublicense, use and filing of patent applications for the BCM technology. BCM's technology is also subject to U.S. governmental rights to call for a license to exploit the technology. If we fail to get such approvals or rights, our ability to use and/or profit from products that incorporate the BCM technology may be inhibited or prevented. If we fail to perform any of our obligations under the BCM license agreement, the BCM license agreement may be terminated. If the BCM license agreement is terminated, the licensed technology could revert to BCM, which may impair our ability to use or further develop our products candidates.

We have obtained a worldwide license to patents for variants of Factor VIII from the Regents of the University of Michigan (University of Michigan). We intend to use such variants to further our research and development with respect to our HEMODURE Biopump. If we breach our payment or development obligations under such license agreement, University of Michigan would have the right to terminate the license and we would be unable to use such licensed patents.

Our business is dependent on proprietary rights that may be difficult to protect and such dependence could affect our ability to effectively compete.

In addition to our patents, we also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position especially where we do not believe that patent protection is appropriate or obtainable. However, others, including our competitors, may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. We take precautionary measures to protect our proprietary rights and information, including the use of confidentiality agreements with employees and consultants, and those with whom we have academic and commercial relationships. However, we may not have such agreements in place with all such parties and, in spite of the measures, there can still be no guarantee that agreements will not be violated or that there will be an adequate remedy available for a violation of an agreement. Any of these events could prevent us from developing or commercializing our product candidates. Trade secrets are by nature difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and/or know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, we have no trademark or applications pending and third parties may have trademarks or pending applications on our contemplated marks, similar marks, or in confusingly similar fields of use (or may be using our contemplated marks or similar marks). We may have to change our use of certain marks which could have an adverse impact on our business and may require us to spend additional funds to develop new marks. We anticipate that we will spend both time and management resources to develop and file trademark applications in the future.

We are subject to intense competition in the therapeutic protein market from companies with greater resources and more mature products, which may result in our competitors developing or commercializing products before or more successfully than us.

While we believe our Biopump Platform Technology has significant advantages, there are a number of well-established and substantial companies engaged in the development, production, marketing, sale and distribution of products that are potentially competitive with our product candidates or the Biopump Platform Technology in general. Many of these companies are more experienced than our company is and represent significant competition. It is also possible that other parties have in development products substantially similar to or with properties that are more efficacious, less invasive and more cost effectively delivered than our product candidates or the Biopump Platform Technology in general. The success of our competitors in developing, bringing to market, distributing and selling their products could negatively affect our result of operations and/or general acceptance of our product candidates.

We face risks related to the general economic conditions that may adversely affect our business.

In general, our operating results can be significantly and adversely affected by negative economic conditions, high labor, material and commodity costs and unforeseen changes in demand for our products and services. These conditions have resulted and could continue to result in slower adoption of new technologies and cost containment efforts by governments and other payers for healthcare research and development, products and services.

The grants we received from the Israeli Office of the Chief Scientist place certain restrictions on us.

Through our wholly owned Israeli subsidiary, we have received \$8,622,000, of grants from the Israeli Office of the Chief Scientist (OCS). The grant agreements require repayment of the grants provided to us through the payment of royalties out of income received from commercializing the developed technology. Pursuant to the Israeli Encouragement of Industrial Research and Development Law, certain limitations will apply to the change of control of the grant recipient and the financing, mortgaging, production, exportation, licensing and transfer or sale of its technology and intellectual property to third parties, which will require the Chief Scientist's prior consent and, in case such a third party is outside of Israel, extended royalties and/or other fees. This could have a material adverse effect on and significant cash flow consequences to our company if, and when, any technologies, intellectual property or manufacturing rights are exported, transferred or licensed to third parties outside Israel. If the OCS does not wish to give its consent in any required situation or transaction, we would need to negotiate a resolution with the OCS. In any event, such a transaction, assuming the OCS approved it, would involve monetary payments, such as royalties or fees, of not less than the applicable funding received from the OCS plus interest and, in aggregate, not to exceed six times the applicable funding received from the OCS.

Health care policy changes, including U.S. health care reform legislation signed in 2010, may have a material adverse effect on us.

Health care reform is often a subject of attention in governments that are trying to control health care expenditures. Health care reform proposals have been the subject of much debate in the U.S. Congress and some state legislatures, as well as in other countries. There is no assurance that legislation or underlying rules and guidelines resulting in adverse effects on our company or our product candidates will not be adopted in a country in which we intend to operate and/or upon the distribution of our product candidates in the United States.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (ACA) and the Health Care and Education Reconciliation Act of 2010. The legislation imposes significant new taxes on medical device makers in the form of a 2.3% excise tax on all U.S. medical device sales that began January 1, 2013. Under the law, the total cost to the medical device industry from the tax is expected to be approximately \$29 billion over ten years. This significant increase in the tax burden on our industry could have a material, negative impact on our results of operations and our cash flows, especially if the Biopump was determined to be a medical device. Other elements of this legislation, such as comparative effectiveness research, an independent payment advisory board, payment system reforms, including shared savings pilots, and other provisions, could meaningfully change the way health care is developed and delivered, and may materially impact numerous aspects of our business.

Reimbursement policies of third-party payers may negatively affect the acceptance of our product candidates by subjecting the product candidates to sales and pharmaceutical pricing controls.

Third-party payers (Medicare, Medicaid, private health insurance companies and other organizations) may affect the pricing or relative attractiveness of our product candidates by regulating the level of reimbursement provided to the physicians and clinics utilizing our product candidates or by refusing reimbursement. If reimbursement under these programs, or if the amount of time to secure reimbursement is too long, our ability to market our technology and product candidates may be adversely and materially affected. In international markets, reimbursement by private third-party medical insurance providers, including government insurers and independent providers, varies from country to country. In certain countries, our ability to achieve significant market penetration may depend upon the availability of third-party government reimbursement. Pharmaceutical pricing is also subject to regulation in Israel as well as other countries within which we may wish to distribute our product candidates.

The ACA reduces Medicare and Medicaid payments to hospitals, clinical laboratories and pharmaceutical companies, and could otherwise reduce the volume of medical procedures. Further, the Budget Control Act enacted in August 2011 committed the U.S. federal government to significantly reduce the federal deficit over ten years. In addition to placing caps on discretionary spending through 2021, the Budget Control Act also established a budget sequestration that calls for automatic spending cuts over a nine-year period. Across-the-board spending cuts went into effect on March 1, 2013, and Medicare spending cuts that reduce Part A and Part B payments by 2% went into effect on April 1, 2013. Further, the Bipartisan Budget Act of 2013, passed in December 2013, extends the sequestration automatic Medicare spending cuts to 2023 from 2021. Although we cannot predict the full effect on our business of the implementation of existing legislation such as the ACA and the Budget Control Act, or the enactment of additional legislation, we believe that legislation or regulation that reduces reimbursement for our products could adversely affect how much or under what circumstances health care providers will prescribe or administer our products. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

We may experience product liability claims, which could adversely affect our business and financial condition.

We may become subject to product liability claims. We have not experienced any product liability claims to date; however, the production at commercial scale, distribution, sale and support of our product candidates may entail the risk of such claims, which is likely to be substantial in light of the use of our product candidates in the treatment of medical conditions. We carry product liability insurance coverage in connection with our human trial of the EPODURE Biopump, including the new viral vector and implantation protocol which is projected to be conducted in Israel. Our insurance provides \$5 million in coverage, subject to a \$5,000 deductible. Our insurance must be renewed annually at a current cost of \$17,000 per year to cover current and planned trials in Israel. If we are unable to obtain a renewal or if we suffer a successful product liability claim in excess of our insurance coverage, such claim could result in significant monetary liability and could have a material adverse impact on our business, operations, financial position and/or reputation.

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

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our results of operation could be harmed.

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accounting firm addressing these assessments. We continuously monitor our existing internal controls over financial reporting systems to confirm that they are compliant with Section 404, and we may identify deficiencies that we may not be able to remediate in time to meet the deadlines imposed by the Sarbanes-Oxley Act. This process may divert internal resources and will take a significant amount of time and effort to complete.

If at any time it is determined that we are not in compliance with Section 404, we may be required to implement new internal control procedures and reevaluate our financial reporting. We may experience higher than anticipated operating expenses as well as increased independent auditor fees during the implementation of these changes and thereafter. Further, we may need to hire additional qualified personnel. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, which could result in our being unable to obtain an unqualified report on internal controls from our independent auditors. Failure to maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses, divert management's attention from operating our business which could have a material adverse effect on our business.

There have been changing laws, regulations and standards relating to corporate governance and public disclosure, as well as new regulations promulgated by the SEC and rules promulgated by the national securities exchanges, including the NYSE MKT. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Our board members, principal executive officer and principal financial officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could have a material adverse effect on our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, we may incur additional expenses to comply with standards set by regulatory authorities or governing bodies which would have a material adverse effect on our business, financial condition and results of operations.

Security breaches and other disruptions to our information technology infrastructure could interfere with our operations or clinical trials, compromise information belonging to us and our suppliers and expose us to liability, which could adversely impact our business and reputation.

In the ordinary course of business, we rely on information technology networks and systems, some of which are managed by third parties, to process, transmit and store electronic information, and to manage or support a variety of business processes and activities, including the conduct of our clinical trials. Additionally, we collect and store sensitive data, including proprietary business information. Despite security measures and business continuity plans, our information technology networks and infrastructure may be vulnerable to damage, disruptions or shutdowns due to attack by hackers or breaches, employee error or malfeasance, power outages, computer viruses, telecommunication or utility failures, systems failures, natural disasters or other catastrophic events. Any such event could result in legal claims or proceedings, liability or penalties under privacy laws, disruption in operations and damage to our reputation, which could adversely affect our business.

Risk Related to our Securities

Our securities are thinly traded, resulting in relative illiquidity and price volatility, and there may not ever be an active market for our securities in the United States.

Although our common stock has been admitted for trading on the AIM Market since December 2007 and our common stock and a class of our warrants have been traded on the NYSE MKT (formerly the NYSE Amex) since April 2011, the volumes and trading in our securities have been extremely sporadic. As a result, the ability of holders to purchase or sell our securities is limited, with low-volume trading creating wide shifts in price. For our securities to continue to be listed on the NYSE MKT, we must meet the current listing requirements of that exchange. If we were unable to meet these requirements, our securities could be delisted from the NYSE MKT. Any such delisting of our securities could have an adverse effect on the market price of, and the efficiency of the trading market for, our securities, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and less coverage of us by securities analysts, if any. Also, if in the future we were to determine that we need to seek additional equity capital, it could have an adverse effect on our ability to raise capital in the public or private equity markets.

Further, the share prices of public companies, particularly those operating in high growth sectors, are often subject to significant fluctuations. The market price of our common stock on the NYSE MKT has been volatile, ranging from \$3.50 per share to \$9.00 per share during the 52-week trading period ending February 17, 2014. We expect that the market price of our common stock will continue to fluctuate significantly due to factors including, but not limited to, the following:

- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- changes in market valuations of companies in our industry;
- general market conditions;
- future issuances of our common stock or other securities; and
- other events or factors, including those beyond our control.

Our common stock is traded on more than one market and this may result in price variations.

Our common stock is currently traded on both the NYSE MKT and the AIM Market. Trading in our shares on these markets takes place in different currencies (U.S. dollars on the NYSE MKT and British Pounds sterling on the AIM Market) and at different times (resulting from different time zones, different trading days and different public holidays in the United States and the United Kingdom). The trading prices of our shares of common stock on these two markets may differ due to these and other factors. Any decrease in the price of our shares of common stock on one of these markets could cause a decrease in the trading price of our shares on the other market. We cannot predict what the effect of trading of our common stock on the AIM Market will be on the trading of our common stock on the NYSE MKT, and vice versa.

Securities analysts may not initiate coverage or continue to cover our common stock, and this may have a negative impact on its market price.

The trading market for our securities could depend in part on the research and reports that securities analysts publish about our business and us. We do not have any control over these analysts. There is no guarantee that securities analysts will cover our securities. If securities analysts do not cover our securities, the lack of research coverage may adversely affect their market prices. If we are covered by securities analysts, and our securities are the subject of an unfavorable report, the prices for our securities would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, we could lose visibility in the financial markets, which could cause our stock price and/or trading volume to decline.

The exercise of options and warrants and other issuances of shares of common stock or securities convertible into or exercisable for shares of common stock will dilute the ownership interests of our current stockholders and may adversely affect the future market price of our common stock.

Sales of our common stock in the public market, either by us or by our current stockholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. Nearly all of the shares of our common stock held by those of our current stockholders who are not affiliates may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act of 1933, as amended, or the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock.

In addition, as of December 31, 2013, there were outstanding options to purchase an aggregate of 6,646,049 shares of our common stock at exercise prices ranging from \$2.49 per share to \$14.50 per share, of which options to purchase 1,552,145 shares were exercisable as of such date. As of December 31, 2013, there were warrants outstanding to purchase 9,241,161 shares of our common stock, at exercise prices ranging from \$0.0002 per share to \$11.16 per share, with a weighted average exercise price of \$6.37 per share, all of which were exercisable as of December 31, 2013. The exercise of options and warrants at prices below the market price of our common stock could adversely affect the price of shares of our common stock. In addition, some of the warrants have anti-dilution protection which will require us to lower the exercise price in the event we sell securities in the future at a price lower than the exercise price then in effect. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

Any issuance of our common stock that is not made solely to then-existing stockholders proportionate to their interests, such as in the case of a stock dividend or stock split, will result in dilution to each stockholder by reducing his, her or its percentage ownership of the total outstanding shares. Moreover, if we issue options or warrants to purchase our common stock in the future and those options or warrants are exercised, stockholders may experience further dilution. In 2013, we issued 4,750,000 options resulting in significant dilution to our existing stockholders. Delaware law and our corporate governance documents do not prohibit the number of options that we may issue in the future, except to the extent we are limited by the number of our authorized shares of common stock which is currently 100,000,000 shares. Holders of shares of our common stock have no preemptive rights that entitle them to purchase their pro rata share of any offering of shares of any class or series.

Our principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of December 31, 2013, our officers and directors together controlled approximately 39.9% of our outstanding common stock on a fully diluted basis. In addition, as of December 31, 2013, our five largest stockholders other than management and the directors controlled approximately 21.8% of our outstanding common stock on a fully diluted basis. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock, and therefore may not be in the best interest of our other stockholders.

We have never declared or paid dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends will be at the discretion of our Board of Directors and will be dependent upon our financial condition, operating results, capital requirements, applicable contractual restrictions and other such factors as our Board of Directors may deem relevant.

Provisions of Delaware law may delay or prevent efforts to acquire a controlling interest in us, even if such acquisition were in the best interests of our stockholders.

We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock. These provisions may also prevent changes in our management.

There may be future sales or other dilution of our equity, which may adversely affect the market price of our common stock.

We will require additional capital in the future to continue and expand our research and development and other operations. We are not restricted from issuing additional shares of our common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, our common stock. The market price of our common stock could decline as a result of sales of shares of our common stock or sales of such other securities or the perception that such sales could occur.

Israel-Related Risks

Our research and development activities occur primarily in Israel, and our company and our business could be adversely affected by the economic, political and military conditions in that region.

Our principal activities are based in Israel, which may be adversely affected by acts of terrorism, major hostilities, adverse legislation or litigation. If major hostilities should occur in the Middle East, including as a result of acts of terrorism in the United States or elsewhere, any such effects may not be covered by insurance. Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East, such as damages to our facilities and the resulting disruption to our ability to continue our product development. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot be certain that this government coverage will be maintained or will be adequate in the event we submit a claim. Any losses or damages incurred by us could have a material adverse effect on our business, financial condition and results of operations.

We are directly affected by economic, political and military conditions in that country. Our Israeli production facilities are located in Misgav which is located approximately 150 miles from the nearest point of the border with the Gaza Strip. Hamas, an Islamist terrorist group, has been responsible for many attacks on Israel, launched from the Gaza Strip, including targeting civilian targets in southern Israel and the western Negev region, as well as Tel Aviv and Jerusalem. These attacks have reduced over time, however, there can be no assurance that this period of relative calm will continue, especially in light of continuing rhetoric between Iran and Israel. There can be no assurance that Hamas will not obtain and use longer-range missiles capable of reaching our facilities, which could result in a significant disruption of the Israel-based portion of our business. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our business, financial condition and results of operations and may make it more difficult for us to raise necessary capital. For example, any major escalation in hostilities in the region could result in a portion of our employees, including executive officers, directors, and key personnel and consultants, being called up to perform military duty for an extended period of time. 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 the agreements.

In addition to the foregoing, since the end of 2010, numerous acts of protest and civil unrest have taken place in several countries in the Middle East and North Africa, many of which involved significant violence. It cannot be predicted how the civil unrest in Egypt and the civil war in Syria or in other countries in the region will affect the political and security situation in the Middle East and on Israel's position within the region.

Our operations may be disrupted by the obligations of our personnel to perform military service which could have a material adverse effect of our business.

Many of our male employees in Israel are obligated to perform up to one month (in some cases more) of annual military reserve duty until they reach the age of 45 and, in the event of a military conflict, could be called to active duty. Our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of military service of one or more of our key employees. A disruption could have a material adverse effect on our business.

Under current U.S. and Israeli law, we may not be able to enforce employees' covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We have entered in non-competition agreements with our key employees. These agreements prohibit our key employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. Under applicable U.S. and Israeli law, we may be unable to enforce these agreements. If we cannot enforce our non-competition agreements with our employees, then we may be unable to prevent our competitors from benefiting from the expertise of our former employees, which could materially adversely affect our business, results of operations and ability to capitalize on our proprietary information.

Service of process and enforcement of civil liabilities on our company and our officers may be difficult.

We are organized under the laws of the State of Delaware and are subject to service of process in the United States. However, certain of our assets are located outside the United States. In addition, certain of our executive officers are residents of Israel and the bulk of the assets of such executive officers may be located outside the United States.

There is doubt as to the enforceability of civil liabilities under the Securities Act and the Securities Exchange Act of 1934, as amended, or the Exchange Act, in original actions instituted in Israel. As a result, it may not be possible for investors to enforce or effect service of process upon these executive officers or to judgments of U.S. courts predicated upon the civil liability provisions of U.S. laws against our assets, as well as the assets of these executive officers. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Israel.

We may experience foreign currency exchange risks, which may increase the dollar costs of our operations in Israel.

A substantial portion of our expenses, including those related to our clinical trial, our research and development, personnel and facilities-related expenses is incurred in New Israeli Shekels (NIS). Inflation in Israel will have the effect of increasing the dollar cost of our operations in Israel, unless it is offset on a timely basis by a devaluation of the NIS relative to the U.S. dollar. This may give rise to an exchange rate risk against NIS. We do not currently engage in hedging or use any other financial instruments or arrangements to manage this risk.

ITEM 1B - Unresolved Staff Comments.

None.

ITEM 2 - Properties.

Our clinical operations are currently primarily conducted in Israel, in leased space of 7,050 sq. ft. located at Turag House, Misgav Business Center (Teradion), D.N. Misgav, Israel. Our principal executive offices are located at 435 Devon Park Drive, Building 700, Wayne, Pennsylvania 19087. We believe that these facilities are adequate to meet our current needs. We believe that if additional or alternative space is needed in the future, such space will be available on commercially reasonable terms as necessary.

ITEM 3 - Legal Proceedings.

We are not currently a party, as plaintiff or defendant, to any legal proceedings which, individually or in the aggregate, are expected by us to have a material effect on our business, financial condition or results of operation if determined adversely to us.

ITEM 4 -Mine Safety Disclosures

Not applicable.

PART II

ITEM 5 - Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock and the series of warrants issued in connection with our U.S. initial public offering in April 2011 are traded, separately, on the NYSE MKT under the symbols "MDGN" and "MDGN.WS," respectively. Our common stock is also listed on the AIM Market, operated by the London Stock Exchange, plc, under the symbols "MEDG" and "MEDU." No other series of our warrants is listed on any exchange.

The following table sets forth, for the periods indicated, the high and low sale prices for our common stock as reported by the NYSE MKT:

	High	Low
2012		
First Quarter (January 1, 2012 to March 31, 2012)	\$ 7.25	\$ 2.50
Second Quarter (April 1, 2012 to June 30, 2012)	12.75	4.25
Third Quarter (July 1, 2012 to September 30, 2012)	16.43	9.31
Fourth Quarter (October 1, 2012 to December 31, 2012)	11.00	6.61
2013		
First Quarter (January 1, 2013 to March 31, 2013)	\$ 8.19	\$ 4.70
Second Quarter (April 1, 2013 to June 30, 2013)	4.99	3.50
Third Quarter (July 1, 2013 to September 30, 2013)	8.01	3.60
Fourth Quarter (October 1, 2013 to December 31, 2013)	7.98	5.32

Holders of Record

As of February 17, 2014, there were 390 holders of record of our common stock. We believe there are a substantially greater number of beneficial holders.

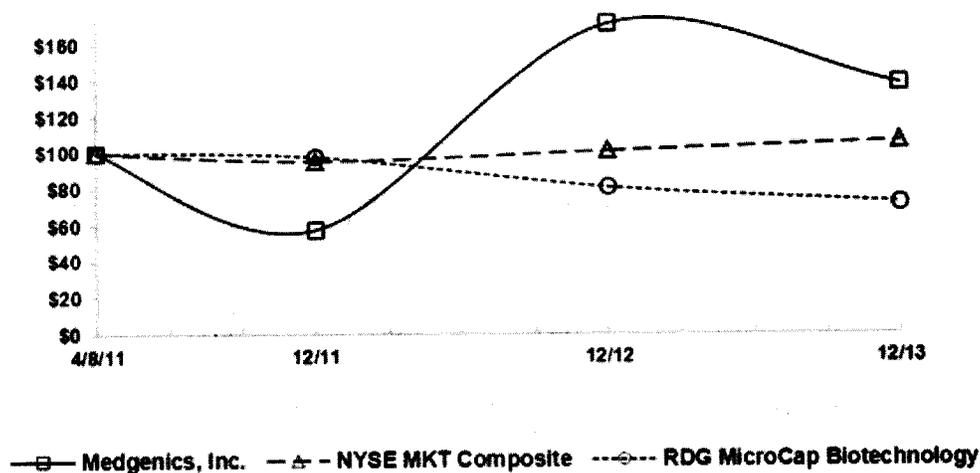
Stock Performance Graph

The following graph compares the cumulative total stockholder return data for our common stock from April 8, 2011 (the date on which our common stock commenced trading on the NYSE MKT) through December 31, 2013 to the cumulative return over such time period of (i) the NYSE MKT Composite Index and (ii) the RDG MicroCap Biotechnology Index. The graph assumes an investment of \$100 on April 8, 2011 in (i) our common stock, (ii) the securities comprising the NYSE MKT Composite Index and (iii) the securities comprising the RDG MicroCap Biotechnology Index, including dividend reinvestment, if any. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.

The material in this section is not "soliciting material," is not deemed "filed" with the SEC and shall not be incorporated by reference by any general statement incorporating by reference this Annual Report on Form 10-K into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent we specifically incorporate this section by reference.

COMPARISON OF 33 MONTH CUMULATIVE TOTAL RETURN*

Among Medgenics, Inc., the NYSE MKT Composite Index, and the RDG MicroCap Biotechnology Index



*\$100 invested on 4-8-11 in stock or 3-31-11 in index, including reinvestment of dividends
Fiscal year ending December 31

Dividends

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board of Directors.

Recent Sales of Unregistered Securities

In the year ended December 31, 2013, the following securities were sold by us without registration under the Securities Act in transactions which have not been previously described in a Quarterly Report on Form 10-Q or Current Report on Form 8-K. The securities described below were deemed exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act. There were no underwriters employed in connection with any of these transactions.

Common Stock Issued Upon Exercise of Outstanding Warrants and Options

In the fourth quarter of 2013, a consultant exercised warrants to purchase 67,230 shares of common stock at an exercise price of \$5.50 per share using the cashless exercise method. Using this cashless exercise method, the consultant was issued 9,499 shares.

Options and Warrants Issued

Warrants to purchase up to 100,000 shares of common stock were issued to a consultant in June 2013 in connection with services rendered under a consulting agreement. These warrants have an exercise price of \$3.76 per share and expire on June 26, 2018.

ITEM 6 - Selected Financial Data.

The selected data presented below under the captions "Statement of Operations Data," "Statement of Cash Flows Data" and "Balance Sheet Data" for, and as of the end of, each of the fiscal years in the five-year period ended December 31, 2013, are derived from, and should be read in conjunction with, our audited consolidated financial statements.

The information contained in this table should also be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes thereto included elsewhere in this report (in thousands of dollars except share and per share data):

	Year Ended December 31,				
	2013	2012	2011	2010	2009
Statement of Operations Data:					
Operating expenses:					
Research and development expenses, net	\$ 7,297	\$ 5,431	\$ 5,052	\$ 1,526	\$ 1,689
General and administrative expenses	10,521	7,197	4,924	4,405	2,534
Other income:					
Excess amount of participation in research and developments from third party	—	—	—	(2,577)	(327)
Operating loss	(17,818)	(12,628)	(9,976)	(3,354)	(3,896)
Financial expenses	(20)	(2,429)	(214)	(1,664)	(3,055)
Financial income	726	5	2,097	873	10
Loss before taxes on income	(17,112)	(15,052)	(8,093)	(4,145)	(6,941)
Taxes on income	17	19	3	2	1
Loss	(17,129)	(15,071)	(8,096)	(4,147)	(6,942)
Basic loss per share	\$ (0.97)	\$ (1.37)	\$ (0.96)	\$ (0.95)	\$ (2.06)
Diluted loss per share	\$ (1.06)	\$ (1.37)	\$ (0.96)	\$ (0.95)	\$ (2.06)
Weighted average number of shares used in computing basic loss per share	17,629,436	11,023,881	8,447,908	4,374,520	3,367,024
Weighted average number of shares used in computing diluted loss per share	17,683,510	11,023,881	8,447,908	4,374,520	3,367,024
Statement of Cash Flows Data:					
Net cash used in operating activities	\$ (12,732)	\$ (8,619)	\$ (8,027)	\$ (4,154)	\$ (1,692)
Net cash used in investing activities	(183)	(63)	(289)	(69)	(26)
Net cash provided by financing activities	28,874	10,118	10,452	6,612	1,145
Increase (decrease) in cash and cash equivalents	15,959	1,436	2,136	2,389	(573)
Balance Sheet Data:					
Cash and cash equivalents	\$ 22,390	\$ 6,431	\$ 4,995	\$ 2,859	\$ 470
Current assets	22,592	6,970	6,117	3,842	481
Long-term assets	495	737	745	607	603
Total assets	23,087	7,707	6,862	5,121	1,084
Current liabilities	3,014	2,350	2,059	7,438	3,420
Long-term liabilities	1,650	3,423	1,806	4,757	5,377
Stockholders' equity (deficit)	18,423	1,934	2,997	(7,074)	(7,713)

ITEM 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

Overview

We are a medical technology and therapeutics company, developing an innovative and proprietary platform technology offering what we believe to be a novel approach for the \$50 billion orphan and rare diseases therapeutics market. Our Biopump Platform Technology is designed to provide sustained protein/peptide therapy to treat a range of chronic diseases and conditions.

Since our inception on January 27, 2000, we have focused our efforts on research and development and clinical trials and have received no revenue from product sales. We have funded our operations principally through equity and debt financings, participation from the Office of the Chief Scientist (OCS) in Israel and a collaborative agreement. Our operations to date have been primarily limited to organizing and staffing our company, developing the Biopump Platform Technology and its applications, developing and initiating clinical trials for our product candidates, and improving and maintaining our patent portfolio.

We have generated significant losses to date, and we expect to continue to generate losses as we progress towards the commercialization of our product candidates. We have incurred net losses of approximately \$17.13 million, \$15.07 million and \$8.10 million for the years ended December 31, 2013, 2012 and 2011, respectively, and approximately \$82.13 million for the period from inception through December 31, 2013. As of December 31, 2013, we had an accumulated deficit of approximately \$81.71 million. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Although we have not yet generated revenues from product sales, we have generated income from partnering on development programs and we expect to expand our partnering activity.

In 2009, we signed a preclinical development and option agreement with Baxter Healthcare, a market leader in the field of hemophilia, representing our first collaboration agreement for the Biopump Platform Technology. Pursuant to this agreement, the healthcare company provided funding for preclinical development of our Biopump Platform Technology to produce and deliver the clotting protein Factor VIII for the sustained treatment of hemophilia. Under the terms of the collaboration agreement, we received \$3.97 million. The agreement expired in 2011.

Recent Equity Offerings:

On April 13, 2011, we completed the United States initial public offering (IPO) of our common stock and redeemable common stock purchase warrants, both listed on the NYSE MKT. We issued 2,624,100 shares of common stock, including 164,100 shares pursuant to the exercise of the underwriters' over-allotment option, at a price of \$4.54 per share and redeemable common stock purchase warrants to purchase 2,829,000 shares including 369,000 warrants pursuant to the exercise of the underwriters' over-allotment option, at a price of \$0.46 per warrant for total gross proceeds of \$13.21 million, or approximately \$10.39 million in net proceeds after deducting underwriting discounts and commissions of \$1.45 million and other offering costs of approximately \$1.37 million.

On the closing date of the IPO (April 13, 2011), \$0.57 million of convertible debentures issued in 2009 (the 2009 Debentures) were automatically converted at a conversion price of \$2.724 per share of common stock into an aggregate 209,656 shares of common stock and we issued 5-year warrants to purchase 84,693 shares of common stock at an initial exercise price of \$4.99 per share in connection with the conversion of the 2009 Debentures. On the same date, \$4.00 million of convertible debentures issued in 2010 (the 2010 Debentures) were automatically converted at a conversion price of \$3.405 per share of common stock into an aggregate 1,198,242 shares of common stock. An additional 2,534 shares of common stock were issued to the holders of the 2010 Debentures in November 2011 to compensate the holders of the 2010 Debentures for a minor portion of the interest which had been accrued but not paid at the time of conversion.

In connection with our IPO, the exercise price of certain warrants and options which were initially issued with round-down protection mechanism were adjusted based upon the share value as determined in the IPO.

On June 18, 2012, we completed a private placement transaction in which we issued an aggregate of 1,944,734 units with each unit consisting of one share of our common stock and a warrant to purchase 0.75 shares of our common stock. The warrants to purchase an aggregate of 1,458,550 shares of common stock were issued with an exercise price of \$8.34 per share, first became exercisable on December 15, 2012 (which, if all were exercised in full, would result in the issuance of 1,458,576 shares of common stock due to the rounding of fractional shares) and will expire on June 18, 2017. In addition, warrants to purchase 194,473 shares of our common stock having an exercise price of \$9.17 per share were issued to the placement agent, first became exercisable on December 18, 2012 and will expire on June 18, 2017. Each unit was sold for a purchase price of \$4.90 for total gross proceeds of approximately \$9.53 million, or approximately \$8.41 million in net proceeds after deducting private placement fees of \$0.95 million and other offering costs of \$0.17 million.

On February 13, 2013, we completed a registered public offering of 5,600,000 shares of common stock and 5,600,000 Series 2013-A warrants to purchase up to an aggregate of 2,800,000 shares of common stock. The shares of common stock and Series 2013-A warrants were sold together as a fixed combination, each consisting of one share of common stock and one Series 2013-A warrant to purchase 0.50 of a share of common stock, at a public offering price of \$5.25 per combination, less the underwriting discounts and commissions payable by us, for net proceeds of approximately \$26.55 million. To cover over-allotments made in connection with the offering, the underwriters purchased, at the same price, an additional 470,000 shares of common stock and an additional 840,000 Series 2013-A warrants to purchase up to 420,000 shares of common stock, for additional net proceeds of approximately \$2.27 million.

The Series 2013-A warrants issued in this offering were immediately exercisable and will expire on February 13, 2018. The initial exercise price of the Series 2013-A warrants is \$6.78 per whole share of common stock. The exercise price and number of shares of common stock issuable upon exercise of the Series 2013-A warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction, among other events as described in the Series 2013-A warrants. However, the Series 2013-A warrants will not be adjusted for any issuances of common stock or securities convertible into or exercisable for common stock at a price below the then current exercise price of the Series 2013-A warrants. In the event of a sale of our company, each holder of Series 2013-A warrants will have the right, exercisable at its option, to require us to purchase such holder's Series 2013-A warrants at a price determined using a Black-Scholes option pricing model under certain circumstances as described in the Series 2013-A warrants.

Financial Operations Overview

Research and Development Expense

Research and development expense consists of: (i) internal costs associated with our development activities; (ii) payments we make to third party contract research organizations, contract manufacturers, clinical trial sites and consultants; (iii) technology and intellectual property license costs; (iv) manufacturing development costs; (v) personnel related expenses, including salaries, and other related costs, including stock-based compensation expense, for the personnel involved in product development; (vi) activities related to regulatory filings and the advancement of our product candidates through preclinical studies and clinical trials; and (vii) facilities and other allocated expenses, which include direct and allocated expenses for rent, facility maintenance, as well as laboratory and other supplies. All research and development costs are expensed as incurred.

Conducting a significant amount of development is central to our business model. Through December 31, 2013, we incurred approximately \$46.50 million in gross research and development expenses since our inception on January 27, 2000. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. We plan to increase our research and development expenses for the foreseeable future in order to complete the proof of concept of our EPODURE Biopump with a new viral vector and implantation protocol, and our earlier-stage research and development projects including in targeted rare and orphan disease indications.

The following table summarizes the percentages of our gross research and development expenses related to our initial two product candidates and other projects. The percentages summarized in the following table reflect expenses directly attributable to each development candidate, which are tracked on a project basis. A portion of our internal costs, including indirect costs relating to our product candidates, are not tracked on a project basis and are allocated based on management's estimate.

	Year Ended December 31,			Period From
	2011	2012	2013	January 27, 2000 (Inception) through December 31, 2013
EPODURE Biopump	50 %	50 %	50 %	70 %
INFRADURE Biopump	25 %	40 %	45 %	21 %
Other Product Candidates	25 %	10 %	5 %	9 %

The process of conducting pre-clinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of these uncertainties, together with the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We are concurrently focusing on proceeding with the approved EPODURE Biopump trial to obtain proof of concept with the new viral vector and new implantation protocol and pursuing pre-clinical research and development in targeted orphan and rare disease.

Research and development expenses are shown net of participation by third parties. In connection with our collaboration with Baxter Healthcare, the excess of the recognized amount received from the healthcare company over the amount of research and development expenses incurred during the period for the collaboration agreement is recognized as other income within operating income.

General and Administrative Expense

General and administrative expense consists primarily of salaries and other related costs, including stock-based compensation expense, for persons serving as our directors and in our executive, finance and accounting functions. Other general and administrative expense includes facility-related costs not otherwise included in research and development expense, costs associated with industry and trade shows, and professional fees for legal services and accounting services. We expect that our general and administrative expenses will increase as we add personnel. Since our inception on January 27, 2000 through December 31, 2013, we spent approximately \$44.12 million on general and administrative expense.

Other Income

We have not generated any product revenue since our inception, but, in connection with our first collaboration agreement, we received \$3.97 million from Baxter Healthcare through December 31, 2011 of which \$2.9 million has been recognized as other income. To date, we have funded our operations primarily through equity and debt financings and funding from the Israeli OCS. If our product development efforts result in clinical success, regulatory approval and successful commercialization of any of our products, we would expect to generate revenue from sales or licenses of any such products.

Financial Income and Expense

Financial expense consists primarily of convertible debentures valuations, warrant valuations and interest and amortization of beneficial conversion feature of convertible note.

Financial income consists primarily of interest earned on our cash and cash equivalents and marketable securities.

Results of Operations for the Years Ended December 31, 2013 and 2012

Research and Development Expenses

Gross research and development expenses for the year ended December 31, 2013 were \$8.87 million, increasing from \$7.19 million in 2012 due to an increase in the use of materials and subcontractors in connection with human EPODURE clinical trials in Israel and preparation for human EPODURE clinical trials in the United States including ongoing method development, as well as an increase in research and development personnel.

Research and development expenses, net for the year ended December 31, 2013 were \$7.30 million, increasing from \$5.43 million in 2012. The increase in the research and development expenses, net was due to the increase in gross research and development expenses as detailed above, in addition to participation by the OCS of \$1.57 million in 2013 compared with \$1.76 million in 2012.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2013 were \$10.52 million, increasing from \$7.20 million in 2012 primarily due to stock-based compensation expenses related to equity granted to directors and executives upon their appointment in 2013, increased professional fees and increased activities in the United States.

Financial Income and Expenses

Financial expenses for year ended December 31, 2013 were \$0.02 million, decreasing from \$2.43 million in 2012. This decrease of \$2.41 million was mainly due to the change in valuation of the warrant liability due to the fluctuation in the market price of our common stock.

Financial income for the year ended December 31, 2013 was \$0.73 million, increasing from de minimis for the same period in 2012. The financial income in 2012 was primarily due to the change in valuation of the warrant liability due to the decrease in the market price of our common stock as compared to the prior period.

Results of Operations for the Years Ended December 31, 2012 and 2011

Research and Development Expenses

Gross research and development expenses for the year ended December 31, 2012 were \$7.19 million, increasing from \$5.99 million in 2011 due to an increase in the use of materials and subcontractors in connection with our ongoing phase II EPODURE clinical trial in Israel, the preparations for the INFRADURE trial in Israel, and the phase II EPODURE clinical trial in the U.S and ongoing method development, as well as an increase in research and development personnel.

Research and development expenses, net for the year ended December 31, 2012 were \$5.43 million, increasing from \$5.05 million in 2011. The increase in the research and development expenses, net was due to the increase in gross research and development expenses as detailed above, which were partially offset by participation by the OCS of \$1.76 million in 2012 compared with \$0.86 million in 2011.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2012 were \$7.20 million, increasing from \$4.92 million in 2011 primarily due to stock-based compensation expenses related to equity granted to the Chairman of the Board upon his appointment in June 2012, increased legal fees and professional services and increased activities in the United States.

Financial Income and Expenses

Financial expenses for year ended December 31, 2012 were \$2.43 million, increasing from \$0.21 million in 2011. This increase of \$2.22 million was mainly due to the change in valuation of the warrant liability during the year ended December 31, 2012 due to the rise in the market price of our common stock as compared to the prior period.

Financial income for the year ended December 31, 2012 was de minimis, decreasing from \$2.10 million for the same period in 2011. The financial income of approximately \$2.10 million in 2011 was primarily due to the change in valuation of the warrant liability due to the decrease in the market price of our common stock as compared to the prior period.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations primarily through a combination of equity, debt issues and grants from the OCS and other third parties.

We recorded \$1.57 million, \$1.76 million and \$0.86 million in the years ended December 31, 2013, 2012 and 2011, respectively, and \$8.62 million from inception through December 31, 2013, from the OCS in development grants.

In the year ended December 31, 2013, options and warrants were exercised in consideration of \$0.01 million and 19,499 shares of common stock were issued upon such exercises. In the year ended December 31, 2012, options and warrants were exercised in consideration of \$1.71 million and 575,349 shares of common stock were issued upon such exercises. In the year ended December 31, 2011, options and warrants were exercised in consideration of \$0.06 million and 380,162 shares of common stock were issued upon such exercises.

On February 13, 2013, we completed a registered public offering of 5,600,000 shares of common stock and 5,600,000 Series 2013-A warrants to purchase up to an aggregate of 2,800,000 shares of common stock. The shares of common stock and Series 2013-A warrants were sold together as a fixed combination, each consisting of one share of common stock and one Series 2013-A warrant to purchase 0.50 of a share of common stock, at a public offering price of \$5.25 per combination, less the underwriting discounts and commissions payable by us, for net proceeds of approximately \$26.55 million. We granted the underwriters the option to purchase, at the same price, an aggregate of up to an additional 840,000 shares of common stock and/or an additional 840,000 Series 2013-A warrants to purchase up to 420,000 shares of common stock as may be necessary to cover over-allotments made in connection with the offering. The underwriters exercised this option in March 2013 with respect to an additional 470,000 shares of common stock and an additional 840,000 Series 2013-A warrants to purchase up to 420,000 shares of common stock, for additional net proceeds of approximately \$2.27 million.

On June 18, 2012, we completed a private placement transaction in which we issued an aggregate of 1,944,734 units with each unit consisting of one share of our common stock and a warrant to purchase 0.75 shares of our common stock. The warrants to purchase an aggregate of 1,458,550 shares of common stock were issued with an exercise price of \$8.34 per share and became exercisable on December 15, 2012 (which, if all were exercised in full, would result in the issuance of 1,458,576 shares of common stock due to the rounding of fractional shares) and will expire on June 18, 2017. In addition, warrants to purchase 194,473 shares of our common stock having an exercise price of \$9.17 per share were issued to the placement agent, became exercisable on December 18, 2012 and will expire on June 18, 2017. Each unit was sold for a purchase price of \$4.90 for total gross proceeds of approximately \$9.53 million, or approximately \$8.41 million in net proceeds after deducting private placement fees of \$0.95 million and other offering costs of \$0.17 million.

On April 13, 2011, we completed our IPO in the United States of our common stock and redeemable common stock purchase warrants which are both listed on the NYSE MKT. We issued 2,624,100 shares of common stock, including 164,100 shares pursuant to the exercise of the underwriters' over-allotment option, at a price of \$4.54 per share and redeemable common stock purchase warrants to purchase 2,829,000 shares, including 369,000 warrants pursuant to the exercise of the underwriters' over-allotment option, at a price of \$0.46 per warrant for total gross proceeds of \$13.21 million or approximately \$10.39 million in net proceeds after deducting underwriting discounts and commissions of \$1.45 million and other offering costs of approximately \$1.37 million. The warrants issued in the IPO have an exercise price of \$6.00 per share of common stock and expire on April 12, 2016. We have certain rights to redeem the warrants issued in the IPO if the last reported sales price for our common stock equals or exceeds \$10.00 per share for 20 trading days within a 30 consecutive trading day period.

On the closing date of the IPO (April 13, 2011), \$0.57 million of 2009 Debentures were automatically converted at a conversion price of \$2.724 per share of common stock into an aggregate amount of 209,656 shares and we issued 5-year warrants to purchase 84,693 shares at an initial exercise price of \$4.99 per share in connection with the conversion of the 2009 Debentures. On the same date, \$4.00 million of 2010 Debentures were automatically converted at a conversion price of \$3.405 per share into an aggregate amount of 1,198,242 shares. An additional 2,534 shares of Common stock were issued to holders of the 2010 Debentures in November 2011 to compensate the 2010 Debenture holders for a minor portion of the interest to compensate the 2010 Debenture holders for a minor portion of the interest which had been accrued but not paid at the time of conversion.

Cash Flows

We had cash and cash equivalents of \$22.39 million at December 31, 2013 and \$6.43 million at December 31, 2012. The increase in our cash balance during 2013 was primarily the result of our registered public offering of common stock and Series 2013-A warrants during the period.

Net cash used in operating activities of \$12.73 million, \$8.62 million and \$8.02 million for the years ended December 31, 2013, 2012 and 2011, respectively, primarily reflected our cash expenses for our operations.

Our cash used in investing activities relates mainly to our purchases of property and equipment.

Net cash provided by financing activities was \$28.87 million, \$10.12 million and \$10.45 million for the years ended December 31, 2013, 2012 and 2011, respectively. Our cash flows from financing activities during the year ended December 31, 2013 were primarily the result of our registered public offering of common stock and Series 2013-A warrants in February 2013 from which the net proceeds were approximately \$28.82 million. Our cash flows from financing activities during the year ended December 31, 2012 were primarily the result of the private placement of common stock and warrants in June 2012 from which the net proceeds were approximately \$8.41 million. Our cash flows from financing activities during the year ended December 31, 2011 were primarily the result of the IPO from which the net proceeds were approximately \$10.39 million.

Funding Requirements

Our future capital requirements will depend on a number of factors, including the success in targeting rare and orphan disease candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the acquisition of licenses to new products or compounds, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates.

Without taking into account any revenue we may receive as a result of licensing or other commercialization agreements, we believe that cash on hand, including the net proceeds we received from our public offering of common stock and Series 2013-A warrants in 2013, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through the second quarter of 2015. We have based this estimate on assumptions that may prove to be wrong and we could use our available resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

We do not anticipate that we will generate revenue from the sale of products for at least four years; however, we do intend to seek licensing or other commercialization agreements for existing and new Biopump applications. In the absence of additional funding or adequate funding from commercialization agreements, we expect our continuing operating losses to result in decreases in our cash balances over the next several quarters.

Absent significant corporate collaboration and licensing arrangements, we will need to finance our future cash needs through public or private equity offerings or debt financings in the future. We do not currently have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them if the conditions for raising capital are favorable. We may seek to encourage holders of our warrants to exercise, sell additional equity or debt securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations.

Our plans include seeking additional investments and commercial agreements to continue our operations. However, there is no assurance that we will be successful in our efforts to raise the necessary capital and/or reach such commercial agreements to continue our planned research and development activities.

Contractual Obligations

The following table sets forth our contractual payment obligations as of December 31, 2013 for the periods indicated below:

Contractual Obligations	Total	Less than 1 Year	1 – 3 Years	3 – 5 Years	More than 5 Years and Thereafter
Long-term severance pay	\$ 439,000	\$ —	\$ —	\$ —	\$ —
Short-term severance pay	\$ 450,000	\$ 450,000	\$ —	\$ —	\$ —
Operating lease obligations	\$ 199,000	\$ 113,000	\$ 86,000	\$ —	\$ —
Purchase obligations	\$ 1,793,000	\$ 929,000	\$ 123,000	\$ 136,000	\$ 605,000
Warrant liability	\$ 1,211,000	\$ —	\$ 1,211,000	\$ —	\$ —
Total	\$ 4,092,000	\$ 1,492,000	\$ 1,420,000	\$ 136,000	\$ 605,000

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant account policies are more fully described in Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Liability in Respect of Warrants

In 2010 we issued warrants with an exercise price denominated in British Pounds Sterling which differs from the functional currency we use. In addition, the exercise price of such warrants is subject to downward adjustment. In addition, in 2006 and 2007, we issued warrants that included price protection in the event of sales of securities below the then current exercise price. In accordance with Accounting Standards Codification No. 815-40-15-71, we classified these warrants as a liability at their fair value. The warrants liability will be remeasured at each reporting period until exercised or expired. The decrease in the fair value of the warrants during the year ended December 31, 2011 of \$2.06 million, the increase in the fair value of the warrants during the year ended December 31, 2012 of \$2.34 million, and the decrease in the fair value of the warrants during the year ended December 31, 2013 of \$0.72 million are reported in the Statements of Operations as financial income and expense, respectively.

We estimate the fair value of these warrants at the respective balance sheet dates using the Binomial option pricing model. We use a number of assumptions to estimate the fair value, including the remaining contractual terms of the warrants, risk-free interest rates, expected dividend yield and expected volatility of the price of the underlying common stock. These assumptions could differ significantly in the future, thus resulting in variability of the fair value which would impact the results of operations in the future.

Stock-Based Compensation

We account for stock options according to the Accounting Standards Codification No. 718 (ASC 718) "Compensation - Stock Compensation." Under ASC 718, stock-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as an expense over the employee's requisite service period on a straight-line basis.

We account for stock options granted to non-employees on a fair value basis using an option pricing method in accordance with ASC 718. The initial non-cash charge to operations for non-employee options with vesting are revalued at the end of each reporting period based upon the change in the fair value of the options and amortized to consulting expense over the related vesting period.

For the purpose of valuing options and warrants granted to our employees, non-employees and directors and officers during the years ended December 31, 2013, 2012 and 2011, we used the Binomial options pricing model. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of our awards. We estimated the expected life of the options granted based on anticipated exercises in the future periods assuming the success of our business model as currently forecast. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for our stock options was calculated by examining historical volatilities for publicly traded industry peers as we do not have sufficient trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for our common stock becomes available. Given the senior nature of the roles of our employees, directors and officers, we currently estimate that we will experience no forfeitures for those options currently outstanding.

Off-Balance Sheet Arrangements

Pursuant to our license agreement with Yissum Research Development Company of the Hebrew University (Yissum), Yissum granted us a license of certain patents for commercial development, production, sublicense and marketing of products to be based on its know-how and research results. In consideration, we agreed to pay Yissum the following amounts, provided, however, that the total aggregate payment of royalties and sublicense fees by us to Yissum shall not exceed \$10 million:

- non-refundable license fee of \$0.4 million to be paid in three installments, as follows:
 - \$0.05 million when the accrued investments in us by any third party after May 23, 2005 equal at least \$3 million (paid in 2007);
 - \$0.15 million when the accrued investments in us by any third party after May 23, 2005 equal at least \$12 million (paid in second quarter of 2010); and
 - \$0.2 million when the accrued investments in us by any third party after May 23, 2005 equal at least \$18 million (paid in April 2011);
- royalties at a rate of 5% of net sales of product incorporating the licensed technology; and
- sublicense fees at a rate of 9% of sublicense considerations received by us.

The Yissum license will expire upon the later of the twentieth anniversary of our first commercial sale of products utilizing the licensed technology and the expiration of the last Yissum patent licensed to us, which is expected to be approximately July 2022.

Under agreements with the OCS in Israel regarding research and development projects, our Israeli subsidiary is committed to pay royalties to the OCS at rates between 3.5% and 5% of the income resulting from this research and development, at an amount not to exceed the amount of the grants received by our subsidiary as participation in the research and development program, plus interest at LIBOR. The obligation to pay these royalties is contingent on actual income and in the absence of such income no payment is required. As of December 31, 2013, the principal amount of the aggregate contingent liability amounted to approximately \$8.62 million.

Pursuant to an agreement we entered into on February 11, 2011 (effective as of January 31, 2011), the Regents of the University of Michigan (Michigan) have granted a worldwide license for patent rights relating to certain uses of variants of clotting Factor VIII. The license agreement covers a portfolio of two issued and three pending patents. In consideration we agreed to pay Michigan the following amounts:

- an initial license fee of \$25,000 which was paid in 2011;
- an annual license fee in arrears of \$10,000 rising to \$50,000 following the grant by us of a sublicense or (if sooner) from the sixth anniversary of the license agreement;
- staged milestone payments of \$750,000 (in aggregate), of which \$400,000 will be creditable against royalties;
- royalties at an initial rate of 5% of net sales, reducing by a percentage point at predetermined thresholds to 2% upon cumulative net sales exceeding \$50 million;
- sublicense fees at an initial rate of 6% of sublicensing revenues, reducing by a percentage point at predetermined thresholds to 4% upon cumulative sublicensing revenues exceeding \$50 million; and
- patent maintenance costs.

The exclusive worldwide license from Michigan is expected to expire in 2027 upon the expiration of the last to expire of the patent rights licensed. As of December 31, 2013, we have paid the initial license fee and patent maintenance costs and an annual license fee. No royalties or sublicense fees have yet accrued with respect to any of these three licenses. Additionally, we cannot estimate when we will begin selling any products that would require us to make any such royalty payments. Whether we will be obligated to make royalty payments in the future is subject to the success of our product development efforts and, accordingly, is inherently uncertain.

ITEM 7A - Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We have no debt outstanding nor do we have any investments in debt instruments other than highly liquid short-term investments. We invest a major portion of our cash surplus in money market funds in the United States. Given the historic low levels of interest rates, we estimate that a further decline in the interest rate we are receiving will not result in a material adverse effect to our business. Accordingly, we consider our interest rate risk exposure to be insignificant at this time.

Foreign Currency Exchange Risk and Inflation

Approximately 30% of our costs, including salaries, lab materials and office expenses, are incurred in NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. We do not believe that inflation has had a material effect on our results of operations for the years ended December 31, 2013, 2012 or 2011, nor do we expect that inflation will have a material impact on our results of operations for the year ending December 31, 2014.

The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Year Ended December 31,		
	2011	2012	2013
Average rate for period	3.578	3.856	3.716
Rate at year-end	3.821	3.733	3.471

Currency fluctuations may affect us by increasing or decreasing costs. Currency fluctuations had no material effect on our results of operations for the years ended December 31, 2011, 2012 and 2013.

To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS. These measures, however, may not adequately protect us from material adverse effects due to the impact of inflation in Israel.

ITEM 8 - Financial Statements and Supplementary Data.

MEDGENICS, INC. AND ITS SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2013

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of

MEDGENICS, INC.
(A Development Stage Company)

We have audited the accompanying consolidated balance sheets of Medgenics, Inc. (a development stage company) ("the Company") and its subsidiary as of December 31, 2012 and 2013, and the related consolidated statements of loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2013 and for the period from January 27, 2000 (inception date) through December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its subsidiary as of December 31, 2012 and 2013 and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 and for the period from January 27, 2000 (inception date) through December 31, 2013, in conformity with accounting principles generally accepted in the United States.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated February 20, 2014, expressed an unqualified opinion thereon.

Tel Aviv, Israel
February 20, 2014

/s/ KOST FORER GABBAY & KASIERER
A Member of EY Global



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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of

MEDGENICS, INC.
(A Development Stage Company)

We have audited Medgenics, Inc. (a development stage company) ("the Company") and its subsidiary internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Medgenics, Inc. and its subsidiary management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, Medgenics, Inc. and its subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Medgenics, Inc. and its subsidiary as of December 31, 2012 and 2013, and the related consolidated statements of loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2013 and for the period from January 27, 2000 (inception date) through December 31, 2013 and our report dated February 20, 2014 expressed an unqualified opinion thereon.

Tel Aviv, Israel
February 20, 2014

/s/ KOST FORER GABBAY & KASIERER
A Member of EY Global

MEDGENICS, INC. AND ITS SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	Note	December 31,	
		2012	2013
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents		\$ 6,431	\$ 22,390
Accounts receivable and prepaid expenses	3	539	202
Total current assets		6,970	22,592
LONG-TERM ASSETS:			
Restricted lease deposits	6(c)	62	42
Severance pay fund		283	96
Property and equipment, net	4	352	357
Deferred issuance expenses		40	-
Total long-term assets		737	495
Total assets		\$ 7,707	\$ 23,087
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Trade payables		\$ 877	\$ 1,062
Other accounts payable and accrued expenses	5	1,473	1,952
Total current liabilities		2,350	3,014
LONG-TERM LIABILITIES:			
Accrued severance pay		1,492	439
Liability in respect of warrants	11	1,931	1,211
Total long-term liabilities		3,423	1,650
Total liabilities		5,773	4,664
COMMITMENTS AND CONTINGENCIES			
	6		
STOCKHOLDERS' EQUITY:			
	7		
Common stock - \$0.0001 par value; 100,000,000 shares authorized; 12,307,808 and 18,497,307 shares issued and outstanding at December 31, 2012 and 2013, respectively		1	2
Additional paid-in capital		66,509	100,126
Deficit accumulated during the development stage		(64,576)	(81,705)
Total stockholders' equity		1,934	18,423
Total liabilities and stockholders' equity		\$ 7,707	\$ 23,087

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

CONSOLIDATED STATEMENTS OF LOSS

U.S. dollars in thousands (except share and per share data)

	Note	Year ended December 31			Period from January 27, 2000 (inception) through December 31, 2013
		2011	2012	2013	2013
Research and development expenses		\$ 5,987	\$ 7,187	\$ 8,870	\$ 46,499
Less:					
Participation by the Office of the Chief Scientist	2(l)	(860)	(1,756)	(1,573)	(8,622)
U.S. Government Grant		-	-	-	(244)
Participation by third party	6(d)	(75)	-	-	(1,067)
Research and development expenses, net		5,052	5,431	7,297	36,566
General and administrative expenses		4,924	7,197	10,521	44,116
Other income:					
Excess amount of participation in research and development from third party	6(d)	-	-	-	(2,904)
Operating loss		(9,976)	(12,628)	(17,818)	(77,778)
Financial expenses	9	(214)	(2,429)	(20)	(4,608)
Financial income	9	2,097	5	726	364
Loss before taxes on income		(8,093)	(15,052)	(17,112)	(82,022)
Taxes on income	8(e)	3	19	17	112
Loss		<u>\$ (8,096)</u>	<u>\$ (15,071)</u>	<u>\$ (17,129)</u>	<u>\$ (82,134)</u>
Basic loss per share	12	<u>\$ (0.96)</u>	<u>\$ (1.37)</u>	<u>\$ (0.97)</u>	
Diluted loss per share	12	<u>\$ (0.96)</u>	<u>\$ (1.37)</u>	<u>\$ (1.06)</u>	
Weighted average number of shares of Common stock used in computing basic loss per share		<u>8,447,908</u>	<u>11,023,881</u>	<u>17,629,436</u>	
Weighted average number of shares of Common stock used in computing diluted loss per share		<u>8,447,908</u>	<u>11,023,881</u>	<u>17,683,510</u>	

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

MEDGENICS, INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

U.S. dollars in thousands (except share and per share data)

	Old Common stock		Series A Preferred stock		Additional paid-in capital	Deferred stock compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balance as of January 27, 2000 (inception)	-	\$ -	-	\$ -	\$ -	\$ -	\$ -	\$ -
Issuance of Old Common stock in January and March 2000 at par value	59,133	(*)	-	-	-	-	-	(*)
Issuance of Old Common stock in August 2000 at \$39.90 per share, net	12,512	-	-	-	500	-	-	500
Issuance of Old Common stock in respect of license agreement in August 2000 at par value	26,884	(*)	-	-	-	-	-	(*)
Loss	-	-	-	-	-	-	(681)	(681)
Balance as of December 31, 2000	98,529	(*)	-	-	500	-	(681)	(181)
Stock split effected as stock dividend	-	(*)	-	-	(*)	-	-	-
Issuance of Preferred stock in January 2001 at \$49.35 per share, net of issuance costs of \$5	-	-	3,957	(*)	195	-	-	195
Issuance of Preferred stock in March and June 2001 at \$58.45 per share, net of issuance costs of \$192	-	-	116,738	(*)	6,806	-	-	6,806
Deferred stock compensation	-	-	-	-	248	(248)	-	-
Amortization of deferred stock compensation	-	-	-	-	-	41	-	41
Stock based compensation expense related to options to consultants	-	-	-	-	511	-	-	511
Loss	-	-	-	-	-	-	(3,244)	(3,244)
Balance as of December 31, 2001	98,529	(*)	120,695	(*)	8,260	(207)	(3,925)	4,128

(*) Represents an amount lower than \$1.

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

MEDGENICS, INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

U.S. dollars in thousands (except share and per share data)

	Old Common stock		Series A Preferred stock		Series B Preferred stock		Additional paid-in capital	Deferred stock compensation	Deficit accumulated during the development stage	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2001	98,529	\$ (*)	120,695	\$ (*)	-	\$ (*)	\$ 8,260	\$ (207)	\$ (3,925)	\$ 4,128
Issuance of Preferred stock in October 2002 at \$68.95 per share, net of issuance costs of \$89	-	-	-	-	76,476	(*)	5,264	-	-	5,264
Deferred stock compensation	-	-	-	-	-	-	64	(64)	-	-
Amortization of deferred stock compensation	-	-	-	-	-	-	-	67	-	67
Stock based compensation expenses related to options to consultants	-	-	-	-	-	-	371	-	-	371
Loss	-	-	-	-	-	-	-	-	(5,049)	(5,049)
Balance as of December 31, 2002	98,529	(*)	120,695	(*)	76,476	(*)	13,959	(204)	(8,974)	4,781
Exercise of stock options	555	(*)	-	-	-	-	(*)	-	-	(*)
Issuance of Preferred stock in April and May 2003 at \$70.00 per share, net of issuance costs of \$97	-	-	-	-	30,485	(*)	2,037	-	-	2,037
Deferred stock compensation	-	-	-	-	-	-	441	(441)	-	-
Amortization of deferred stock compensation	-	-	-	-	-	-	-	105	-	105
Stock based compensation expenses related to options to consultants	-	-	-	-	-	-	475	-	-	475
Loss	-	-	-	-	-	-	-	-	(5,038)	(5,038)
Balance as of December 31, 2003	99,084	(*)	120,695	(*)	106,961	(*)	16,912	(540)	(14,012)	2,360

(*) Represents an amount lower than \$1.

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

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

U.S. dollars in thousands (except share and per share data)

	Old Common stock		Series A Preferred stock		Series B Preferred stock		Additional paid-in capital	Deferred stock compensation	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2003	99,084	(\$*)	120,695	(\$*)	106,961	(\$*)	\$ 16,912	\$ (540)	\$ (14,012)	\$ 2,360
Exercise of stock options	364	(\$*)	-	-	-	-	(*)	-	-	(*)
Stock issued to service providers	952	(\$*)	-	-	-	-	10	-	-	10
Amortization of deferred stock compensation	-	-	-	-	-	-	-	540	-	540
Stock based compensation expenses related to options to consultants	-	-	-	-	-	-	347	-	-	347
Loss	-	-	-	-	-	-	-	-	(4,516)	(4,516)
Balance as of December 31, 2004	100,400	(\$*)	120,695	(\$*)	106,961	(\$*)	\$ 17,269	\$ -	\$ (18,528)	\$ (1,259)
Loss	-	-	-	-	-	-	-	-	(76)	(76)
Balance as of December 31, 2005	100,400	(\$*)	120,695	(\$*)	106,961	(\$*)	\$ 17,269	\$ -	\$ (19,304)	\$ (2,035)

(*) Represents an amount lower than \$1.

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

MEDGENICS, INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

U.S. dollars in thousands (except share and per share data)

	Common stock		Old Common stock		Series A Preferred stock		Series B Preferred stock		Additional paid-in capital	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2005		\$ -	100,400	\$ (*)	120,695	\$ (*)	106,961	\$ (*)	\$ 17,269	\$ (19,304)	\$ (2,035)
Conversion of Old Common stock, Series A and Series B Preferred stock into Common stock	282,452	(*)	(100,400)	(*)	(120,695)	(*)	(106,691)	(*)	(436)	436	-
Conversion of convertible Note into Common stock	342,368	(*)	-	-	-	-	-	-	1,795	-	1,795
Issuance of Common stock as settlement of debt in March 2006	75,235	(*)	-	-	-	-	-	-	96	-	96
Issuance of Common stock and warrants in March, April and June 2006 (\$2.49 per unit of 1 share and 2 warrants), net of issuance costs of \$197	463,358	(*)	-	-	-	-	-	-	952	-	952
Issuance of Common stock and warrants in November and December 2006 (\$4.10 per unit of 1 share and 1.25 warrants), net of issuance costs of \$334	476,736	(*)	-	-	-	-	-	-	1,615	-	1,615
Stock based compensation expense related to options and warrants granted to consultants and employees	-	-	-	-	-	-	-	-	1,161	-	161
Loss	-	-	-	-	-	-	-	-	-	(2,599)	(2,399)
Balance as of December 31, 2006	1,640,149	(*)	-	-	-	-	-	-	\$ 22,432	\$ (21,467)	\$ 985

(*) Represents an amount lower than \$1.

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

MEDGENICS, INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

U.S. dollars in thousands (except share and per share data)

	Common stock		Additional paid-in capital	Receipts on account of shares	Deficit accumulated during the development stage	Total stockholders' equity
	Shares	Amount				
Balance as of December 31, 2006	1,640,149	\$ (*)	\$ 22,452	-	\$ (21,467)	\$ 985
Issuance of Common stock and warrants in January 2007 (\$4.10 per unit of 1 share and 1.25 warrants), net of issuance costs of \$17	12,211	(*)	33	-	-	33
Issuance of Common stock and warrants in May, July and August 2007 (\$5.74 per unit of 1 share and 0.214 warrants), net of issuance costs of \$416	218,498	(*)	835	-	-	835
Exercise of warrants in July 2007	12,912	(*)	-	-	-	(*)
Issuance of Common stock to consultant at fair value of \$18 in August 2007, net	3,492	(*)	(*)	-	-	-
Beneficial conversion feature embedded in convertible note	-	-	511	-	-	511
Issuance of Common stock and warrants in December 2007 (\$6.65 - \$7.35 per unit of 1 share and 0.26 warrants), where applicable, net, related to the admission to AIM	1,086,665	1	4,497	-	-	4,498
Issuance cost due to obligation to issue 4,074 Common stock for consultant, net	-	-	(31)	-	-	(31)
Stock based compensation expense related to options and warrants granted to consultants and employees	-	-	347	-	-	347
Loss	-	-	-	-	(3,851)	(3,851)
Balance as of December 31, 2007	2,973,927	1	28,644	-	(25,318)	3,327
Cashless exercise of warrants in January 2008	70,343	(*)	(*)	-	-	-
Issuance of Common stock to consultant in April 2008	4,074	(*)	31	-	-	31
Exercise of warrants in December 2008	860	(*)	(*)	-	-	-
Stock based compensation related to options and warrants granted to consultants and employees	-	-	436	-	-	436
Receipts on account of stock in respect to exercise of warrants in January 2009	-	-	-	150	-	150
Dividend in respect of reduction in exercise price of certain warrants	-	-	7	-	(7)	-
Loss	-	-	-	-	(4,992)	(4,992)
Balance as of December 31, 2008	3,049,204	1	29,118	150	(30,317)	(1,048)
Exercise of warrants in January and February 2009, net of issuance costs of \$17	315,023	(*)	389	(150)	-	239
Stock based compensation related to options granted to consultants and employees	-	-	520	-	-	520
Issuance of Common stock in October 2009, net at \$3.35 per share, net of issuance costs of \$59	126,285	(*)	364	-	-	364
Receipts on account of shares related to exercise of warrants in January 2010	-	-	-	25	-	25
Dividend in respect of reduction in exercise price of certain Warrants	-	-	3	-	(3)	-
Cumulative effect of reclassification of warrants from equity to liability due to application of ASC 815-40	-	-	(871)	-	-	(871)
Loss	-	-	-	-	(6,942)	(6,942)
Balance as of December 31, 2009	3,490,512	\$ 1	\$ 29,523	\$ 25	\$ (37,262)	\$ (7,713)

(*) Represents an amount lower than \$1.

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

MEDGENICS, INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

U.S. dollars in thousands (except share and per share data)

	Common stock		Additional paid-in capital	Receipts on account of shares	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	Shares	Amount				
Balance as of December 31, 2009	3,490,512	\$ 1	\$ 29,523	\$ 25	\$ (37,262)	\$ (7,713)
Exercise of options and warrants in January, May, September and December	785,419	(*)	559	(25)	-	534
Stock based compensation related to issuance of options and warrants to consultants and employees	-	-	1,834	-	-	1,834
Issuance of Common stock in February to consultants	32,142	(*)	141	-	-	141
Issuance of Common stock in March, net at \$2.63 (GBP 1.75) per share, net of issuance costs of \$135	407,800	(*)	943	-	-	943
Issuance of Common stock in May, net at \$2.52 (GBP 1.75) per share, net of issuance costs of \$87	477,934	(*)	1,115	-	-	1,115
Issuance of Common stock in May at \$3.43 (GBP 2.28) per share	5,502	(*)	19	-	-	19
Issuance of Common stock in August and September to consultants	39,080	(*)	164	-	-	164
Stock based compensation related to the issuance of warrants in September to a consultant	-	-	36	-	-	36
Stock based compensation related to the issuance of restricted Common stock in December to a director	57,142	(*)	(*)	-	-	-
Loss	-	-	-	-	(4,147)	(4,147)
Balance as of December 31, 2010	5,295,531	1	34,334	-	(41,409)	(7,074)
Issuance of Common stock at \$4.54 per share and warrants at \$0.46 per share, net of issuance costs of \$2,826	2,624,100	(*)	10,389	-	-	10,389
Issuance of Common stock and warrants (\$2.72 - \$3.41 per unit of 1 share and 0.06 warrants) upon conversion of debentures	1,410,432	(*)	5,585	-	-	5,585
Stock based compensation related to the issuance of Common stock to a consultant	12,500	(*)	46	-	-	46
Stock based compensation related to the issuance of warrants to consultants	-	-	558	-	-	558
Exercise of options and warrants	380,162	(*)	1,194	-	-	1,194
Stock based compensation related to options and warrants granted to consultants and employees	-	-	395	-	-	395
Loss	-	-	-	-	(8,096)	(8,096)
Balance as of December 31, 2011	9,722,725	\$ 1	\$ 52,501	\$ -	\$ (49,505)	\$ 2,997

(*) Represents an amount lower than \$1.

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

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

U.S. dollars in thousands (except share and per share data)

	Common stock		Additional paid-in capital	Deficit accumulated during the development stage	Total stockholders' equity
	Shares	Amount			
Balance as of December 31, 2011	9,722,725	\$ 1	\$ 52,501	\$ (49,305)	\$ 2,997
Stock based compensation related to issuance of restricted Common stock to directors in January 2012	35,000	(*)	55	-	55
Stock based compensation related to issuance of Common stock to consultants in March and June 2012	30,000	(*)	204	-	204
Issuance of Common stock and warrants (\$4.90 per unit of 1 share and 0.75 warrants) in June 2012, net	1,944,734	(*)	8,407	-	8,407
Exercise of options and warrants	575,349	(*)	2,594	-	2,594
Stock based compensation related to options and warrants granted to consultants and employees	-	-	2,748	-	2,748
Loss	-	-	-	(15,071)	(15,071)
Balance as of December 31, 2012	12,307,808	1	66,509	(64,576)	1,934
Issuance of Common stock and warrants at \$5.24 per share and \$0.01 per warrant	6,070,000	1	28,820	-	28,821
Stock based compensation related to the issuance of Common stock to consultants (**)	55,000	-	548	-	548
Stock based compensation related to the issuance and vesting of restricted Common stock to directors	45,000	-	388	-	388
Exercise of warrants and options	19,499	-	13	-	13
Stock based compensation related to options and warrants granted to consultants and employees	-	-	3,848	-	3,848
Loss	-	-	-	(17,129)	(17,129)
Balance as of December 31, 2013	18,497,307	2	100,126	(81,705)	18,423

(*) Represents an amount lower than \$1.

(**) Includes stock based compensation for an additional 25,000 shares which were not issued as of December 31, 2013.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31			Period from January 27, 2000 (inception) through December 31, 2013
	2011	2012	2013	2013
CASH FLOWS FROM OPERATING ACTIVITIES:				
Loss	\$ (8,096)	\$ (15,071)	\$ (17,129)	\$ (82,134)
Adjustments to reconcile loss to net cash used in operating activities:				
Depreciation	98	145	177	1,403
Loss from disposal of property and equipment	-	-	1	331
Stock based compensation related to options, warrants, common shares and restricted shares granted to employees, directors and consultants	395	3,007	4,784	14,969
Interest and amortization of beneficial conversion feature of convertible note	-	-	-	759
Changes in fair value of convertible debentures and warrants	(1,936)	2,336	(720)	3,258
Accrued severance pay, net	300	140	(416)	793
Exchange differences on a restricted lease deposit and on a long-term loan	4	(5)	-	1
Change in operating assets and liabilities:				
Accounts receivable and prepaid expenses	533	543	360	(219)
Trade payables	764	(26)	185	1,666
Other accounts payable and accrued expenses	(79)	317	29	2,049
Restricted lease deposits	(10)	(5)	(3)	(63)
Net cash used in operating activities	<u>(8,027)</u>	<u>(8,619)</u>	<u>(12,732)</u>	<u>(57,187)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of property and equipment	(289)	(63)	(186)	(2,268)
Proceeds from disposal of property and equipment	-	-	3	176
Net cash used in investing activities	<u>\$ (289)</u>	<u>\$ (63)</u>	<u>\$ (183)</u>	<u>\$ (2,092)</u>

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31			Period from January 27, 2000 (inception) through December 31 2013
	2011	2012	2013	
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of shares and warrants, net	\$ 10,389	\$ 8,407	\$ 28,861	\$ 71,769
Proceeds from exercise of options and warrants, net	63	1,711	13	2,735
Repayment of a long-term loan	-	-	-	(73)
Proceeds from long-term loan	-	-	-	70
Issuance of convertible debentures and warrants	-	-	-	7,168
Net cash provided by financing activities	10,452	10,118	28,874	81,669
Increase in cash and cash equivalents	2,136	1,436	15,959	22,390
Balance of cash and cash equivalents at the beginning of the period	2,859	4,995	6,431	-
Balance of cash and cash equivalents at the end of the period	\$ 4,995	\$ 6,431	\$ 22,390	\$ 22,390
Supplemental disclosure of cash flow information:				
Cash paid during the period for:				
Interest	\$ 49	\$ -	\$ -	\$ 242
Taxes	\$ 1	\$ 50	\$ 17	\$ 165
Supplemental disclosure of non-cash flow information:				
Issuance expenses paid with shares	\$ -	\$ -	\$ -	\$ 310
Issuance of Common stock upon conversion of convertible debentures	\$ 5,585	\$ -	\$ -	\$ 8,430
Classification of liability in respect of warrants into equity due to the exercise of warrants	\$ 1,131	\$ 883	\$ -	\$ 2,014

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

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 1:- GENERAL

- a. Medgenics, Inc. (the "Company") was incorporated in January 2000 in Delaware. The Company has a wholly-owned subsidiary, Medgenics Medical Israel Ltd. (the "Subsidiary"), which was incorporated in Israel in March 2000. The Company and the Subsidiary are engaged in the research and development of products in the field of biotechnology and associated medical equipment and are thus considered development stage companies as defined in Accounting Standards Codification ("ASC") topic number 915, "*Development Stage Entities*" ("ASC 915").

The Company's Common stock is traded on the NYSE MKT (formerly NYSE Amex) and on the AIM market of the London Stock Exchange ("AIM").

- b. The Company and the Subsidiary are in the development stage. As reflected in the accompanying consolidated financial statements, the Company incurred a loss of \$17,129 during the year ended December 31, 2013 and has an accumulated deficit of \$81,705 as of December 31, 2013. The Company and the Subsidiary have not yet generated revenues from product sale. In the past, the Company generated income from partnering on development programs and expects to expand its partnering activity. Management's plans also include seeking additional investments and commercial agreements to continue the operations of the Company and the Subsidiary.

The Company believes that the net proceeds of the underwritten public offering in February 2013, plus its existing cash and cash equivalents, should be sufficient to meet its operating and capital requirements into the second quarter of 2015.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements are prepared in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP"), applied on a consistent basis, as follows:

- a. Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions. The Company's management believes that the estimates and assumptions used are reasonable based upon information available at the time they are made. These estimates and assumptions can affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

- b. Financial statements in U.S. dollars:

The majority of the Company and the Subsidiary's research and development operations are currently conducted in Israel; however, it is anticipated that the majority of the Company's revenues will be generated outside Israel and will be denominated in U.S. dollars ("dollars"), and financing activities including equity transactions and cash investments, are made mainly in dollars. The Company's management believes that the dollar is the primary currency of the economic environment in which the Company and its Subsidiary operate. Thus, the functional and reporting currency of the Company and the Subsidiary is the dollar.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Accordingly, transactions and balances denominated in dollars are presented at their original amounts. Non-dollar transactions and balances have been re-measured to dollars, in accordance with ASC 830, "Foreign Currency Matters" of the Financial Accounting Standards Board ("FASB"). All exchange gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the Statements of Loss as financial income or expenses, as appropriate.

c. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and the Subsidiary. Intercompany transactions and balances have been eliminated upon consolidation.

d. Cash equivalents:

The Company and the Subsidiary consider all highly liquid investments originally purchased with maturities of three months or less to be cash equivalents.

e. Property and equipment:

Property and equipment are stated at cost net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets.

The annual rates of depreciation are as follows:

	%
Furniture and office equipment	6 - 15 (mainly 15)
Computers and peripheral equipment	33
Laboratory equipment	15 - 33 (mainly 15)
Leasehold improvements	The shorter of term of the lease or the useful life of the asset

f. Impairment of long-lived assets:

Long-lived assets are reviewed for impairment in accordance with ASC 360, "Property, Plant, and Equipment" ("ASC 360"), whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of the asset to the future undiscounted cash flows expected to be generated by the asset. If such an asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. For the period from January 27, 2000 (inception) through December 31, 2013, no impairment losses have been identified.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

g. Severance pay:

The Subsidiary's liability for severance pay is calculated pursuant to the Israeli severance pay law based on the most recent salary for the employees multiplied by the number of years of employment, as of the balance sheet date. Employees are entitled to one month salary for each year of employment or a portion thereof. In addition, several employees are entitled to additional severance compensation as per their employment agreements. The Subsidiary's liability for all of its employees is fully provided by an accrual and is mainly funded by monthly deposits with insurance policies.

The deposited funds may be withdrawn only upon the fulfillment of the obligation pursuant to Israeli severance pay law or labor agreements. The value of the deposited funds is based on the cash surrender value of these policies and includes profits or losses as appropriate. The value of these deposits is recorded as an asset in the Company's balance sheet.

As part of employment agreements, the Subsidiary and most of its employees agreed to the terms set forth in Section 14 of the Israeli Severance Pay Law, according to which amounts deposited in severance pay funds by the Subsidiary shall be the only severance payments released to the employee upon termination of employment, voluntarily or involuntarily. Accordingly, the financial statements do not include the severance pay fund and the severance pay accrual in connection with these employees.

Severance expenses for the years ended December 31, 2011, 2012 and 2013 and for the period from January 27, 2000 (inception) through December 31, 2013, amounted to \$382, \$318, \$186 and \$2,384, respectively.

h. Income taxes:

The Company accounts for income taxes in accordance with ASC 740, "*Income Taxes*" ("ASC 740"). ASC 740 prescribes the use of the liability method whereby deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value. As of December 31, 2013, a full valuation allowance was provided by the Company.

The Company also accounts for income taxes in accordance with ASC 740-10, "*Accounting for Uncertainty in Income Taxes*" ("ASC 740-10"). ASC 740-10 contains a two-step approach for recognizing and measuring uncertain tax positions accounted for in accordance with ASC 740-10. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. As of December 31, 2012 and 2013, no liability has been recorded as a result of ASC 740-10.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

i. Accounting for stock based compensation:

The Company applies ASC 718, "*Compensation-Stock Compensation*" ("ASC 718") which requires the measurement and recognition of compensation expense based on estimated fair values for all share-based payment awards made to employees and directors.

The Company recognized compensation expenses for awards granted based on the straight line method over the requisite service period of each of the grants, net of estimated forfeitures.

In 2011, 2012 and 2013, the Company estimated the fair value of stock options granted to employees and directors using the Binominal options pricing model with the following assumptions:

	2011	2012	2013
Dividend yield	0%	0%	0%
Expected volatility	75%	77%	78-83%
Risk-free interest rate	2.9%	1.7%	1.41-2.75%
Suboptimal exercise factor	1.5-2	1.5	1-1.5
Contractual life (years)	10	5-10	5-10

The Company uses historical data to estimate pre and post vesting exit rate within the valuation model; separate groups of employees that have similar historical exercise behavior are considered separately for valuation purposes.

The suboptimal exercise factor represents the value of the underlying stock as a multiple of the exercise price of the option which, if achieved, results in exercise of the option.

The risk-free interest rate assumption is based on observed interest rates appropriate for the term of the Company's stock options.

The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

The Company applies ASC 718 and ASC 505-50, "*Equity-Based Payments to Non-Employees*" ("ASC 505-50"), with respect to options issued to non-employees. ASC 718 requires the use of option valuation models to measure the fair value of the options. The fair value of these options was estimated at grant date and at the end of each reporting period, using the Binomial option pricing model with the following assumptions:

	2011	2012	2013
Dividend yield	0%	0%	0%
Expected volatility	68%	80%	80-82%
Risk-free interest rate	1.7%	1.1%	2.7-3.0%
Contractual life (years)	1.1-9.7	2.4-9.9	8.3-9.8

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

j. Loss per share:

Basic loss per share is computed based on the weighted average number of shares of Common stock outstanding during each year. Diluted loss per share is computed based on the weighted average number of shares of Common stock outstanding during each year, plus the dilutive effect of options, warrants and restricted shares considered to be outstanding during each year, in accordance with ASC 260, "Earnings Per Share" ("ASC 260").

k. Research and development expenses, net:

All research and development expenses are charged to the Consolidated Statements of Loss as incurred. Grants from the Office of the Chief Scientist in Israel ("OCS") and the U.S. government and participation from third-parties related to such research and development expenses are offset against the expense at the later of when receipt is assured or the expenses are incurred.

l. Grants and participation:

Royalty-bearing grants from the OCS for funding approved research and development projects are recognized at the time the Subsidiary is entitled to such grants, on the basis of the costs incurred, and are presented as a deduction from research and development expenses.

Participation from third parties in the Company's research and development operations was recognized at the time the Company was entitled to such participation from the third parties, and is presented as a deduction from the Company's research and development expenses.

The Company recognizes income in its Consolidated Statements of Loss as follows:

- Participation from third party - in accordance with ASC 605-35 based on hours incurred assigned to the project. The excess of the recognized amount received from the Healthcare company over the amount of research and development expenses incurred during the period was recognized as other income within operating income.
- Grants from the U.S. government's QTDP for funding approved research and development projects were recognized at the time the Company was entitled to such grants, on the basis of the costs incurred and are presented as a deduction from research and development expenses.

In May 2013, the Subsidiary received approval for an additional Research and Development program from the OCS for the period December 2012 through November 2013. The approval allows for a grant of up to approximately \$2,100 based on research and development expenses, not funded by others, of up to \$3,780. As of December 31, 2013, \$1,776 was received.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

m. Concentrations of credit risks:

Financial instruments that potentially subject the Company and the Subsidiary to concentrations of credit risk consist principally of cash and cash equivalents.

Cash and cash equivalents are invested in major banks and financial institutions in Israel and the United States. Such deposits in the United States may be in excess of insured limits and are not insured in other jurisdictions. Management believes that the financial institutions that hold the Company's and the Subsidiary's investments are institutions with high credit standing and accordingly, minimal credit risk exists with respect to these investments.

The Company has no off-balance-sheet concentrations of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

n. Fair value of financial instruments:

The carrying amount of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The liability in respect of warrants is presented at fair value.

The Company applies ASC 820, "*Fair Value Measurements and disclosures*" ("ASC 820"). ASC 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants.

As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 Inputs- Quoted prices for identical instruments in active markets.

Level 2 Inputs - Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable.

Level 3 Inputs- Valuation derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

The financial instruments carried at fair value on the Company's balance sheet as of December 31, 2012 and 2013 are warrants with down-round protection classified as a liability. See Note 11.

o. Reclassifications:

Certain financial statement data for prior periods has been reclassified to conform to current year financial statement presentation.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 3:- ACCOUNTS RECEIVABLE AND PREPAID EXPENSES

	December 31,	
	2012	2013
Grant receivable from the OCS	\$ 203	\$ -
Government authorities	83	70
Prepaid expenses and other	253	132
	<u>\$ 539</u>	<u>\$ 202</u>

NOTE 4:- PROPERTY AND EQUIPMENT, NET

Composition of property and equipment is as follows:

	December 31,	
	2012	2013
Cost:		
Furniture and office equipment	\$ 119	\$ 122
Computers and peripheral equipment	65	98
Laboratory equipment	413	554
Leasehold improvements	356	360
Total cost	<u>953</u>	<u>1,134</u>
Total accumulated depreciation	<u>601</u>	<u>777</u>
Depreciated cost	<u>\$ 352</u>	<u>\$ 357</u>

Depreciation expenses for the years ended December 31, 2011, 2012 and 2013 and for the period from January 27, 2000 (inception) through December 31, 2013 amounted to \$98, \$145, \$177 and \$1,403, respectively.

NOTE 5:- OTHER ACCOUNTS PAYABLE AND ACCRUED EXPENSES

	December 31,	
	2012	2013
Employees and payroll accruals	\$ 1,063	\$ 1,506
Accrued expenses and others	410	446
	<u>\$ 1,473</u>	<u>\$ 1,952</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 6:- COMMITMENTS AND CONTINGENCIES

a. License agreements:

1. In 2005, the Company signed an agreement with Yissum Research and Development Company of the Hebrew University of Jerusalem ("Yissum"). According to the agreement, Yissum granted the Company a license of certain patents for commercial development, production, sub-license and marketing of products to be based on its know-how and research results. In consideration, the Company agreed to pay Yissum the following amounts:
 - a) Three milestone payments totaling \$400 were fully paid through April 2011.
 - b) Royalties at a rate of 5% of net sales of the product.
 - c) Sub-license fees at a rate of 9% of sublicense considerations.

The total aggregate payment of royalties and sub-license fees by the Company to Yissum shall not exceed \$10,000. No payments of royalties or sub-license fees were paid through December 31, 2013.

2. Pursuant to an agreement entered into in 2011, the Regents of the University of Michigan ("Michigan") have granted an exclusive worldwide license for patent rights relating to certain uses of variants of clotting Factor VIII. In consideration, the Company agreed to pay Michigan the following amounts:
 - a) an initial license fee of \$25 which was paid in 2011;
 - b) an annual license fee in arrears of \$10 rising to \$50 following the grant by the Company of a sub-license or (if sooner) from the 6th anniversary of the effective date of the license agreement;
 - c) staged milestone payments of \$750 (in aggregate), of which \$400 will be recoupable against royalties;
 - d) royalties at an initial rate of 5% of net sales, reducing by a percentage point at predetermined thresholds to 2% upon cumulative net sales exceeding \$50,000;
 - e) sub-license fees at an initial rate of 6% of sub-licensing revenues, reducing by a percentage point at predetermined thresholds to 4% upon cumulative sub-licensing revenues exceeding \$50,000; and
 - f) patent maintenance costs.

The exclusive worldwide license is expected to expire in 2027 upon the expiration of the last to expire of the patent rights licensed. Total payments under the agreement amounted to \$123, \$42 and \$39 in the years 2011, 2012 and 2013, respectively.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 6:- COMMITMENTS AND CONTINGENCIES (Cont.)

b. Chief Scientist:

Under agreements with the OCS in Israel regarding research and development projects, the Subsidiary is committed to pay royalties to the OCS at rates between 3.5% and 5% of the income resulting from this research and development, at an amount not to exceed the amount of the grants received by the Subsidiary as participation in the research and development program, plus interest at LIBOR. The obligation to pay these royalties is contingent on actual income and in the absence of such income no payment is required. As of December 31, 2013, the principal amount of the aggregate contingent liability was \$8,622.

c. Lease Agreement:

1. The facilities of the Subsidiary are rented under an operating lease agreement for a period ending December 2014. Future minimum lease commitment under the existing non-cancelable operating lease agreement is approximately \$67 for 2014.

As of December 31, 2013 the Subsidiary pledged a bank deposit which is used as a bank guarantee at an amount of \$24 to secure its payments under the lease agreement.

2. The offices of the Company are rented under an operating lease agreement and are cancelable by either party with 60 days' notice. Future minimum lease commitment under the existing operating lease agreement is \$11. The Company's previous offices were leased through January 2014 and an agreement was reached whereby the Company paid, in 2014, \$9 as compensation for the remaining term of the lease.

3. The Subsidiary leases vehicles under standard commercial operating leases. Future minimum lease commitments under various non-cancelable operating lease agreements in respect of motor vehicles are as follows:

Year	\$
2014	113
2015	71
2016	15
	\$ 199

As of December 31, 2013, the Subsidiary paid three months lease installments in advance which amounted to \$33.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 6:- COMMITMENTS AND CONTINGENCIES (Cont.)

- d. In 2009, the Company signed a preclinical development agreement (the "Agreement"), with a major international healthcare company (the "Healthcare company") that is a market leader in the field of hemophilia. The Agreement included funding for preclinical development of the Company's Biopump™ protein technology to produce and deliver the clotting protein Factor VIII for the sustained treatment of hemophilia.

The Company recognized the proceeds as a reduction to research and development expenses in its Consolidated Statements of Loss based on hours incurred assigned to the project. The excess of the recognized amount received from the Healthcare company over the amount of research and development expenses incurred during the period for the Agreement was recognized as other income within operating income.

The Agreement expired in September 2011. The Company received all rights to the jointly developed intellectual property and is obligated to pay royalties to the Healthcare company at the rates between 5% and 10% of any future income arising from such intellectual property up to a maximum of ten times the total funds paid by the Healthcare company to the Company.

Payments totaling \$3,971 were received by the Company from the Healthcare company through 2011.

- e. In 2013, three executives joined the Company. Per their employment agreements, if terminated without cause, these executives will be entitled to severance pay in the aggregate amount of \$2,975.

NOTE 7:- STOCKHOLDERS' EQUITY

- a. Common stock:

The Common stock confers upon the holders the right to receive notice to participate and vote in annual and special meetings of the stockholders of the Company and the right to receive dividends, if declared.

- b. Issuance of shares, stock options and warrants to investors:

1. On April 13, 2011 the Company completed the initial public offering in the United States of its Common stock on the NYSE MKT (formerly NYSE Amex). The Company issued 2,624,100 shares of Common stock, including 164,100 shares pursuant to the exercise of the underwriters' over-allotment option, at a price of \$4.54 per share and warrants to purchase 2,829,000 shares, including 369,000 warrants pursuant to the exercise of the underwriters' over-allotment option, at a price of \$0.46 per warrant for total gross proceeds of \$13,215 or \$10,389 in net proceeds after deducting underwriting discounts and commissions of \$1,454 and other offering costs of \$1,372. These warrants, which were issued with an exercise price of \$6.00 per share and will expire on April 12, 2016, are listed on the NYSE MKT.
2. In June 2012, the Company completed a private placement transaction in which the Company issued 1,944,734 units with each unit consisting of one share of the Company's Common stock and a warrant to purchase 0.75 of one share of Common stock. The warrants to purchase 1,458,550 of Common stock were issued with an exercise price of \$8.34 per share, first became exercisable on December 15, 2012 (which, if all were exercised in full, would result in the issuance of 1,458,576 shares of Common stock due to the rounding of fractional shares) and will expire on June 18, 2017. In addition, warrants to purchase 194,473 shares of Common stock having an exercise price of \$9.17 per share were issued to the placement agent, first became exercisable on December 18, 2012 and will expire on June 18, 2017. Each unit was sold for a purchase price of \$4.90 for total gross proceeds of \$9,529 or \$8,407 in net proceeds after deducting private placement fees of \$953 and other offering costs of \$169.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 7:- STOCKHOLDERS' EQUITY (Cont.)

3. In February 2013, the Company completed an underwritten public offering of 5,600,000 shares of Common stock and Series 2013-A warrants to purchase up to an aggregate of 2,800,000 shares of Common stock. The shares and the warrants were sold together as a fixed combination at a price to the public of \$5.25 per fixed combination. Each combination consisted of one share of Common stock and a warrant to purchase one-half of a share of Common stock at an exercise price of \$6.78 per share. These warrants will expire on February 13, 2018. In March 2013, the underwriters exercised their option and purchased 470,000 shares of Common stock at \$5.24 per share and 840,000 warrants (to purchase up to an aggregate of 420,000 shares) at \$0.01 per warrant. Gross proceeds were \$31,871 or approximately \$28,821 in net proceeds after deducting underwriting discounts and commissions of \$2,550 and other offering costs of approximately \$500.
- c. Issuance of stock options warrants and restricted stock to employees and directors:
1. In 2006, the Company adopted a stock incentive plan (the "stock incentive plan") according to which options, restricted stock and other awards related to Common stock of the Company may be granted to directors, employees and consultants (non-employees) of the Company and the Subsidiary, as determined by the Company's Board of Directors from time to time. The options outstanding are exercisable within a designated period from the date of grant and at an exercise price, each as determined by the Company's Board of Directors. The options outstanding to employees, directors and consultants will vest over a period of two to four years from the date of grant. Any option which is cancelled or forfeited before expiration becomes available for future grants.

In March 2013, the Company's Board of Directors approved an amendment to the stock incentive plan increasing the number of shares of Common stock authorized for issuance thereunder to a total of 4,178,571 shares of Common stock, subject to stockholder approval. The Company's stockholders approved the amendment at the Company's annual meeting of stockholders on April 30, 2013.

In 2012 and 2013, the Company granted 4,100,000 stock options, outside the stock incentive plan, to directors and employees as inducement for joining the Company.
 2. In September 2013, upon the resignation of our former CEO, the Company caused his unvested options to become fully vested as of his separation date (September 13, 2013), and all options vested as of the separation date will be exercisable through the one-year anniversary of his separation date. The Company recorded an additional expense in the amount of \$120 in 2013.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 7:- STOCKHOLDERS' EQUITY (Cont.)

3. A summary of the Company's activity for shares of restricted stock granted to employees and directors is as follows:

Restricted shares

Number of shares of restricted stock as of December 31, 2010	57,142
Vested in 2011	-
Granted in 2011	-
Number of shares of restricted stock as of December 31, 2011	57,142
Vested in 2012	(31,785)
Granted in 2012	35,000
Number of shares of restricted stock as of December 31, 2012	60,357
Vested in 2013	(49,285)
Granted in 2013	45,000
Number of shares of restricted stock as of December 31, 2013	56,072

4. A summary of the Company's activity for options and warrants granted to employees and directors is as follows:

	Number of options and warrants	Weighted average exercise price	Weighted average remaining contractual terms (years)	Aggregate intrinsic value
Outstanding at December 31, 2010	1,878,141	\$ 4.13		
Granted	347,714	\$ 3.73		
Exercised	(112,932)	\$ 3.01		
Forfeited	(34,135)	\$ 2.49		
Outstanding at December 31, 2011	2,078,788	\$ 4.17	4.96	\$ 11
Granted	1,060,254	\$ 10.01		
Exercised	(396,722)	\$ 7.22		
Forfeited	(62,783)	\$ 5.40		
Outstanding at December 31, 2012	2,679,537	\$ 6.01	4.98	\$ 7,159
Granted	4,725,000	\$ 4.73		
Exercised	(3,500)	\$ 3.64		
Forfeited	(34,994)	\$ 5.45		
Outstanding at December 31, 2013	7,366,043	\$ 5.19	7.06	\$ 11,279
Vested and expected to vest, December 31, 2013	7,110,831	\$ 5.20	7.00	\$ 10,941
Exercisable at December 31, 2013	2,344,424	\$ 5.50	3.26	\$ 4,596

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 7:- STOCKHOLDERS' EQUITY (Cont.)

The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's Common stock fair value as of December 31, 2011, 2012 and 2013 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2012 and 2013, respectively.

Calculation of aggregate intrinsic value is based on the closing share price of the Company's Common stock as reported on the NYSE MKT as of December 31, 2011 (\$2.50 per share), December 31, 2012 (\$7.44 per share) and December 31, 2013 (\$5.99 per share), respectively.

The weighted average grant date fair value of options and warrants granted to employees and directors during the years ended December 31, 2011, 2012 and 2013 was \$10.01, \$3.73 and \$4.73, respectively.

As of December 31, 2013, there was \$9,860 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted to employees and directors. That cost is expected to be recognized over a weighted-average period of 2.0 years.

d. Issuance of shares, stock options and warrants to consultants:

1. In September 2011, the Company issued to a consultant 12,500 shares of Common stock in compensation for investor relation services. Total compensation, measured as the grant date fair market value of the stock, amounted to \$46 and was recorded as an operating expense in the Consolidated Statement of Loss in 2011.
2. In March 2012, the Company issued 30,000 shares of Common stock to a consultant. Total compensation, measured as the grant date fair market value of the stock, amounted to \$204 and was recorded as an operating expense in the Consolidated Statement of Loss in 2012.
3. In January 2013, the Company issued a total of 55,000 shares of Common stock to two consultants. Total compensation, measured as the grant date fair market value of the stock, amounted to \$548 and was recorded as an operating expense in the Consolidated Statement of Loss in 2013. As part of the agreement with a consultant, the Company has an obligation to issue an additional 25,000 shares for services received during 2013.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 7:- STOCKHOLDERS' EQUITY (Cont.)

4. A summary of the Company's activity for options granted under the stock incentive plan and warrants to consultants is as follows:

	Number of warrants and options	Weighted average exercise price	Weighted average remaining contractual terms (years)	Aggregate intrinsic value price
Outstanding at December 31, 2010	558,292	\$ 5.04		
Granted	249,446	\$ 4.93		
Exercised	(183,684)	\$ 2.25		
Forfeited	(83,716)	\$ 6.46		
Outstanding at December 31, 2011	<u>540,338</u>	<u>\$ 5.49</u>	<u>3.72</u>	<u>\$ -</u>
Granted	278,045	\$ 8.80		
Exercised	(3,255)	\$ 5.34		
Forfeited	(293,224)	\$ 5.43		
Outstanding at December 31, 2012	<u>521,904</u>	<u>\$ 7.29</u>	<u>4.81</u>	<u>\$ 548</u>
Granted	150,000	\$ 4.39		
Expired	(25,000)	\$ 7.56		
Exercised(*)	(67,230)	\$ 5.50		
Outstanding at December 31, 2013	<u>579,674</u>	<u>\$ 6.72</u>	<u>4.75</u>	<u>\$ 433</u>
Exercisable at December 31, 2013	<u>507,389</u>	<u>\$ 6.71</u>	<u>4.16</u>	<u>\$ 424</u>

(*) Exercised cashlessly upon which 9,499 shares of Common stock were issued.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 7:- STOCKHOLDERS' EQUITY (Cont.)

The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's Common stock fair value as of December 31, 2011, 2012 and 2013 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2012 and 2013, respectively.

Calculation of aggregate intrinsic value is based on the closing share price of the Company's Common stock as reported on the NYSE MKT as of December 31, 2011 (\$2.50 per share), December 31, 2012 (\$7.44 per share) and December 31, 2013 (\$5.99 per share), respectively.

The weighted average grant date fair value of options and warrants granted to consultants during the years ended December 31, 2011, 2012 and 2013 was \$10.01, \$3.73 and \$4.39, respectively.

As of December 31, 2013, there was \$440 of total unrecognized compensation cost related to share-based compensation arrangements granted to consultants. That cost is expected to be recognized over a weighted-average period of 1.1 years.

e. Compensation expenses:

Compensation expense related to shares, warrants and options granted to employees, directors and consultants was recorded in the Consolidated Statements of Loss in the following line items:

	Year ended December 31,		
	2011	2012	2013
Research and development expenses	\$ 78	\$ 225	\$ 450
General and administrative expenses	317	2,782	4,334
	<u>\$ 395</u>	<u>\$ 3,007</u>	<u>\$ 4,784</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 7:- STOCKHOLDERS' EQUITY (Cont.)

f. Summary of options and warrants:

A summary of all the options and warrants outstanding, segregated into ranges, as of December 31, 2013 is presented in the following table:

Options / Warrants	Exercise Price per Share (\$)	As of December 31, 2013		Weighted Average Remaining Contractual Terms (in years)
		Options and Warrants Outstanding	Options and Warrants Exercisable	
Granted to Employees and Directors	2.49-3.14	499,806	386,306	4.1
	3.64-4.99	3,653,629	137,915	9.1
	5.13-7.25	1,197,967	135,740	8.3
	8.19-14.50	1,109,451	779,273	4.0
		<u>6,460,853</u>	<u>1,439,234</u>	
Granted to Consultants	4.20-5.13	34,634	24,447	4.1
	6.65-8.19	144,916	86,582	7.9
	14.50	5,646	1,882	8.5
		<u>185,196</u>	<u>112,911</u>	
Total Options		<u>6,646,049</u>	<u>1,552,145</u>	
Warrants:				
Granted to Employees and Directors	2.49	905,190	905,190	2.2
Granted to Consultants	3.19-4.01	161,370	161,370	3.7
	4.99	31,635	31,635	3.9
	9.17-11.16	201,473	201,473	3.5
		<u>394,478</u>	<u>394,478</u>	
Granted to Investors	0.0002	35,922	35,922	2.2
	4.54-6.00	3,233,521	3,233,521	2.2
	6.78-8.34	7,885,550 (*)	7,885,550 (*)	4.2
		<u>11,154,993</u>	<u>11,154,993</u>	
Total Warrants		<u>12,454,661</u>	<u>12,454,661</u>	
Total Options and Warrants		<u>19,100,710</u>	<u>14,006,806</u>	

(*) Includes 6,427,000 Warrants to purchase 3,213,500 shares of Common stock.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 8:- TAXES ON INCOME

a. Tax laws applicable to the Company and the Subsidiary:

1. The Company is taxed under U.S. tax law.
2. The Subsidiary is taxed under the Israeli income tax law.

Results of the Subsidiary for tax purposes are measured and reflected in nominal NIS. The difference between the rate of change in nominal NIS value and the rate of change in the NIS/U.S. dollar exchange rate causes a difference between taxable income or loss and the income or loss before taxes reflected in the financial statements. In accordance with ASC 740-10, the Company has not provided deferred income taxes on this difference between the reporting currency and the tax bases of assets and liabilities.

3. The Law for the Encouragement of Capital Investments, 1959 (the "ECI Law"):

According to the ECI Law, the Subsidiary is entitled to various tax benefits by virtue of the "beneficiary enterprise" status granted to part of its enterprises, as implied by this ECI Law. The principal benefits by virtue of the ECI Law are tax benefits and reduced tax rates.

The Subsidiary has chosen the alternative track under the ECI Law. Under this track, the Subsidiary is tax exempt for ten years within the benefit period on part of its taxable income.

The income qualifying for tax benefits under the alternative track is the taxable income of a company that has met certain conditions as determined by the ECI Law ("a beneficiary company"), and which is derived from an industrial enterprise. The ECI Law specifies the types of qualifying income that is entitled to tax benefits under the alternative track whereby income from an industrial enterprise includes, among others, revenues from the production and development of software products and revenues from industrial research and development activities performed for a foreign resident (and approved by the Head of the Administration of Industrial Research and Development).

The benefit period starts at the later of the year elected (2011) and the first year the Subsidiary earns taxable income provided that 12 years have not passed since the beginning of the year of election as allowed for companies in development area A. The Subsidiary is located in development area A.

If a dividend is distributed out of tax exempt profits, as above, the Subsidiary will become liable for tax at the rate applicable to its profits from the beneficiary enterprise in the year in which the income was earned, as if it was not under the alternative track. The Company currently does not have tax exempt profits as the period of benefits has not commenced yet.

The above benefits are conditional upon the fulfillment of the conditions stipulated by the ECI Law, regulations published thereunder and the letters of approval for the investments in the approved enterprises, as above. Non-compliance with the conditions may cancel all or part of the benefits and refund of the amount of the benefits, including interest. The Company's management believes that the Subsidiary is meeting the aforementioned conditions.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 8:- TAXES ON INCOME (Cont.)

b. Tax rates applicable to the Company and the Subsidiary:

1. The Subsidiary:

The Israeli corporate tax rate was 24% in 2011 and 25% in 2012 and 2013.

On July 30, 2013, the Israeli Parliament (the Knesset) approved the second and third readings of the Economic Plan for 2013-2014 ("Amended Budget Law") which consists, among others, of fiscal changes whose main aim is to enhance long-term collection of taxes. These changes include, among others, raising the Israeli corporate tax rate from 25% to 26.5% commencing January 1, 2014.

2. The Company:

The tax rates applicable to the Company whose place of incorporation is the U.S. are corporate (progressive) tax at the rate of up to 35%, excluding state tax, which rates depend on the state in which the Company conducts its business.

c. Tax assessments:

The Company files income tax returns in the U.S. federal jurisdiction and state jurisdiction. The U.S. tax authorities have not conducted an examination in respect of the Company's U.S. federal income tax returns since inception. The Subsidiary has tax assessments, deemed final under the law, up to and including the year 2008.

d. Carryforward losses for tax purposes:

As of December 31, 2013, the Company had U.S. federal net operating loss carryforward for income tax purposes in the amount of approximately \$44,400. Net operating loss carryforward arising in taxable years beginning after January 2000 (inception date) can be carried forward and offset against taxable income for 20 years and expiring between 2020 and 2033. As of December 31, 2013 the Company had net operating loss carryforward for California state franchise tax purposes of approximately \$42,900 which can be carried forward and offset against taxable income for 10-20 years, expiring between 2013 and 2033. The Company does not currently have operations in California.

Utilization of U.S. net operating losses may be subject to substantial annual limitations due to the "change in ownership" provisions of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

The Subsidiary has accumulated losses for tax purposes as of December 31, 2013, in the amount of approximately \$22,000, which may be carried forward and offset against taxable income and capital gain in the future for an indefinite period.

e. Taxes on income included in the Consolidated Statements of Loss:

Taxes on income derive from tax prepayments on non-deductible expenses in Israel.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 8:- TAXES ON INCOME (Cont.)

f. Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	December 31,	
	2012	2013
Deferred tax assets:		
Net operating loss carryforward	\$ 13,190	\$ 19,191
Allowances and reserves	526	497
Total deferred tax assets before valuation allowance	13,716	19,688
Valuation allowance	(13,716)	(19,688)
Net deferred tax asset	\$ -	\$ -

As of December 31, 2013, the Company and the Subsidiary have provided valuation allowances in respect of deferred tax assets resulting from tax loss carryforward and other temporary differences, since they have a history of operating losses and current uncertainty concerning their ability to realize these deferred tax assets in the future. Management currently believes that it is more likely than not that the deferred tax regarding the loss carryforward and other temporary differences will not be realized in the foreseeable future.

In 2011, 2012 and 2013, the main reconciling item of the statutory tax rate of the Company and the Subsidiary (25% to 35% in 2012 and 26.5% to 35% in 2013) to the effective tax rate (0%) is tax loss carryforwards and other deferred tax assets for which a full valuation allowance was provided.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 9:- FINANCIAL INCOME (EXPENSE)

	Year ended December 31,			Period from January 27, 2000 (inception) through December 31,
	2011	2012	2013	2013
Financial expenses:				
Bank charges	\$ (17)	\$ (14)	\$ (19)	\$ (122)
Interest expenses	(71)	-	-	(380)
Interest and amortization of beneficial conversion feature of convertible note	-	-	-	(759)
Warrant valuation	-	(2,336)	-	(1,210)
Convertible debentures valuation	(125)	-	-	(2,040)
Foreign currency remeasurement adjustments	-	(76)	-	(76)
Others	(1)	(3)	(1)	(21)
	<u>\$ (214)</u>	<u>\$ (2,429)</u>	<u>\$ (20)</u>	<u>\$ (4,608)</u>
Financial income:				
Foreign currency remeasurement adjustments	\$ 28	\$ -	\$ 2	\$ 85
Warrant valuation	2,061	-	720	-
Interest on cash equivalents, short-term bank deposits and others	8	5	3	229
Others	-	-	1	50
	<u>\$ 2,097</u>	<u>\$ 5</u>	<u>\$ 726</u>	<u>\$ 364</u>

NOTE 10:- DIRECTOR COMPENSATION

	2011 Director Compensation			
	Fees earned or Paid in Cash	Option Awards	Stock Awards	Total
Eugene Bauer, M.D.	\$ -	\$ -	\$ -	\$ -
Isaac Blech	\$ 7	\$ -	\$ -	\$ 7
Gary Allan Brukardt (*)	\$ 11	\$ 26 (1)	\$ -	\$ 37
Alastair Clemow, Ph.D.	\$ 14	\$ 26 (1)	\$ -	\$ 40
Joel Stephen Kanter	\$ 16	\$ 26 (1)	\$ -	\$ 42
Stephen Devon McMurray, M.D.	\$ 14	\$ 26 (1)	\$ -	\$ 40
Andrew L. Pearlman, Ph.D.	\$ -	\$ 128 (2)	\$ -	\$ 128
	<u>\$ 62</u>	<u>\$ 232</u>	<u>\$ -</u>	<u>\$ 294</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 10:- DIRECTOR COMPENSATION (Cont.)

	2012 Director Compensation			
	Fees earned or Paid in Cash	Option Awards	Stock Awards	Total
Sol Barer, Ph.D.	\$ 7	\$ 4,181 (3)	\$ -	\$ 4,188
Eugene Bauer, M.D.	\$ -	\$ -	\$ -	\$ -
Isaac Blech	\$ 28	\$ 17 (4)	\$ 18 (5)	\$ 63
Gary Allan Brukardt (*)	\$ 19	\$ 17 (4)	\$ 18 (5)	\$ 54
Alastair Clemow, Ph.D.	\$ 29	\$ 17 (4)	\$ 18 (5)	\$ 64
Joel Stephen Kanter	\$ 33	\$ 17 (4)	\$ 18 (5)	\$ 68
Stephen Devon McMurray, M.D.	\$ 28	\$ 17 (4)	\$ 18 (5)	\$ 63
Andrew L. Pearlman, Ph.D.	\$ -	\$ -	\$ -	\$ -
	\$ 144	\$ 4,266	\$ 90	\$ 4,500

	2013 Director Compensation			
	Fees earned or Paid in Cash	Option Awards	Stock Awards	Total
Sol Barer, Ph.D.	\$ 27	\$ 935 (6)	\$ 53 (5)	\$ 1,015
Eugene Bauer, M.D.	\$ -	\$ 189 (7)	\$ -	\$ 189
Isaac Blech	\$ 26	\$ 255 (8)	\$ 53 (5)	\$ 334
Alastair Clemow, Ph.D.	\$ 33	\$ 255 (8)	\$ 53 (5)	\$ 341
Michael F. Cola	\$ -	\$ 3,423 (9)	\$ -	\$ 3,423
Wilbur H. Gantz III	\$ -	\$ 734 (10)	\$ -	\$ 734
Joseph Grano, Jr.	\$ 20	\$ 775 (11)	\$ -	\$ 795
Joel Stephen Kanter	\$ 33	\$ 255 (8)	\$ 53 (5)	\$ 341
Stephen Devon McMurray, M.D.	\$ 26	\$ 255 (8)	\$ 53 (5)	\$ 334
Andrew L. Pearlman, Ph.D.	\$ -	\$ -	\$ -	\$ -
	\$ 165	\$ 7,076	\$ 265	\$ 7,506

(*) Deceased.

- (1) Represents the fair value of options to purchase 12,857 shares of Common stock under the stock incentive plan at an exercise price of \$6.55 per share. Such options have a 10-year term and vest in equal installments over three years.
- (2) Represents the fair value of options to purchase 80,000 shares of Common stock under the stock incentive plan at an exercise price of \$3.14 per share. Such options have a 10-year term and vest in equal installments over four years.
- (3) Represents the fair value of options to purchase 900,000 shares of Common stock granted as an inducement outside the stock incentive plan at an exercise price of \$10.80 per share. Such options have a 5-year term. 300,000 of such options vested immediately and the remaining options vesting in equal installments over two years.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 10:- DIRECTOR COMPENSATION (Cont.)

- (4) Represents the fair value of options to purchase 15,000 shares of Common stock under the stock incentive plan at an exercise price of \$2.66 per share. Such options have a 10-year term and vest in equal installments over three years.
- (5) Represents the fair value of 7,000 shares of restricted stock as of the date of grant.
- (6) Represents the fair value of options to purchase 15,000 shares of Common stock under the stock incentive plan at an exercise price of \$7.25 per share and 400,000 shares of Common stock under the stock incentive plan at an exercise price of \$5.22 per share. Such options have a 10-year term and vest in equal installments over three years.
- (7) Represents the fair value of options to purchase 50,000 shares of Common stock under the stock incentive plan at an exercise price of \$6.70 per share. Such options have a 10-year term and vest in equal installments over three years.
- (8) Represents the fair value of options to purchase 15,000 shares of Common stock under the stock incentive plan at an exercise price of \$7.25 per share and 50,000 shares of Common stock under the stock incentive plan at an exercise price of \$6.70 per share. Such options have a 10-year term and vest in equal installments over three years.
- (9) Represents the fair value of options to purchase 1,500,000 shares of Common stock granted as an inducement outside the stock incentive plan at an exercise price of \$4.22 per share. Such options have a 10-year term and vest over three years, one third vesting on the first anniversary of the grant and balance vesting in equal increments on a monthly basis thereafter. These options were granted pursuant to Mr. Cola's employment agreement.
- (10) Represents the fair value of options to purchase 300,000 shares of Common stock under the stock incentive plan at an exercise price of \$6.29 per share. Such options have a 5-year term with 100,000 shares of Common Stock underlying such options vesting immediately and the remaining underlying options vesting in equal installments over two years.
- (11) Represents the fair value of options to purchase 300,000 shares of Common stock under the stock incentive plan at an exercise price of \$4.99 per share. Such options have a 5-year term with 100,000 shares of Common Stock underlying such options vesting immediately and the remaining underlying options vesting in equal installments over two years.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 11:- FAIR VALUE MEASUREMENTS

The Company classified certain warrants with down-round protection issued to investors through the years 2006 and 2007 and warrants issued to the purchasers of convertible debentures in 2010 as a liability at their fair value according to ASC 815-40-15-71. The liability in respect of these warrants is remeasured at each reporting period until exercised or expired. Changes in the fair value of these warrants are reported in the Consolidated Statements of Loss as financial income or expense.

The fair value of these warrants was estimated at December 31, 2011, 2012 and 2013 using the Binomial pricing model with the following assumptions:

	December 31,		
	2011	2012	2013
Dividend yield	0%	0%	0%
Expected volatility	19.1-77.8%	78.1%	78.1%
Risk-free interest rate	0.1-0.5%	0.3%	0.3%
Contractual life (in years)	0.4-3.7	2.7	1.7

The changes in level 3 liabilities measured at fair value on a recurring basis:

	Fair value of liability in respect of warrants
Balance as of December 31, 2010	\$ 3,670
Classification of liability in respect of warrants into equity due to the exercise of warrants	(1,131)
Change in the liability in respect of warrants	<u>(2,061)</u>
Balance as of December 31, 2011	478
Classification of liability in respect of warrants into equity due to the exercise of warrants	(883)
Change in the liability in respect of warrants	<u>2,336</u>
Balance as of December 31, 2012	1,931
Change in the liability in respect of warrants	<u>(720)</u>
Balance as of December 31, 2013	<u>\$ 1,211</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands

NOTE 12:- LOSS PER SHARE

Details in the computation of diluted loss per share:

	Year ended December 31,					
	2011		2012		2013	
	Weighted average number of shares	Loss	Weighted average number of shares	Loss	Weighted average number of shares	Loss
For the computation of basic loss	<u>8,447,908</u>	<u>\$ 8,069</u>	<u>11,023,881</u>	<u>\$ 15,071</u>	<u>17,629,436</u>	<u>\$ 17,129</u>
Effect of potential dilutive common shares issuable upon exercise of warrants classified as liability	- (*)	- (*)	- (*)	- (*)	54,074	1,615 (**)
For the computation of diluted loss	<u>8,447,908</u>	<u>\$ 8,069</u>	<u>11,023,881</u>	<u>\$ 15,071</u>	<u>17,683,510</u>	<u>\$ 18,744</u>

(*) Anti-dilutive.

(**) Financial income resulted from changes in fair value of warrants classified as liability.

The total weighted average number of shares related to the outstanding options, warrants and restricted shares excluded from the calculations of diluted loss per share due to their anti-dilutive effect was 6,188,017, 7,820,950 and 14,838,907 for the years ended December 31, 2011, 2012 and 2013, respectively.

NOTE 13:- SUBSEQUENT EVENTS

Subsequent to the balance sheet date, in January 2014, the Company granted 15,000 options and 7,000 shares of restricted Common stock to each of 8 non-executive Directors of the Company. These shares of Common stock are restricted in that they may not be disposed of and are not entitled to dividends. 50% of these shares were vested the day after the grant and 50% will vest one year from the grant date. All of the options are for a term of 10 years, vest in three equal installments and have an exercise price of \$6.50 per share. These options and restricted Common stock were granted under the stock incentive plan.

ITEM 9 - Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

ITEM 9A - Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Exchange Act Rule 13a-15(b), in connection with the filing of this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2013, the end of the period covered by this report.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework set forth in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework). Based on our evaluation under the framework set forth in *Internal Control — Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2013. Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, the independent registered public accounting firm that audited the financial statements included in this Annual Report on Form 10-K, has issued an attestation report on our internal control over financial reporting as of December 31, 2013, which is included herein.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B - Other Information.

None.

PART III

ITEM 10 - Directors, Executive Officers and Corporate Governance.

Information required by Item 10 is incorporated by reference to our definitive proxy statement for our annual stockholders' meeting presently scheduled to be held in April 2014.

ITEM 11 - Executive Compensation.

Information required by Item 11 is incorporated by reference to our definitive proxy statement for our annual stockholders' meeting presently scheduled to be held in April 2014.

ITEM 12 - Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by Item 12 is incorporated by reference to our definitive proxy statement for our annual stockholders' meeting presently scheduled to be held in April 2014.

ITEM 13 - Certain Relationships and Related Transactions, and Director Independence.

Information required by Item 13 is incorporated by reference to our definitive proxy statement for our annual stockholders' meeting presently scheduled to be held in April 2014.

ITEM 14 - Principal Accountant Fees and Services.

Information required by Item 14 is incorporated by reference to our definitive proxy statement for our annual stockholders' meeting presently scheduled to be held in April 2014.

PART IV

ITEM 15 - Exhibits and Financial Statement Schedules.

(a)(1) *Financial Statements.*

	Page No.
Reports of Independent Registered Public Accounting Firm	F-2 – F-3
Consolidated Balance Sheets as of December 31, 2012 and 2013	F-4
Consolidated Statements of Loss for the years ended December 31, 2011, 2012 and 2013 and for the period from January 27, 2000 (inception) through December 31, 2013	F-5
Statements of Changes in Stockholders' Equity (Deficit) for the period from January 27, 2000 (inception) through December 31, 2013	F-6 – F-12
Consolidated Statements of Cash Flows for the years ended December 31, 2011, 2012 and 2013 and for the period from January 27, 2000 (inception) through December 31, 2013	F-13 – F-14
Notes to the Consolidated Financial Statements	F-15 – F-38

(a)(2) *Financial Statement Schedules.* No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or the notes thereto.

(a)(3) *Exhibits.* The list of exhibits filed with or incorporated by reference in this Annual Report on Form 10-K is set forth below.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (previously filed as Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation (previously filed as Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation dated as of February 14, 2011 (previously filed as Exhibit 4.3 to the Company's Post-Effective Amendment No. 1 to Form S-1 on Form S-3 filed July 16, 2012 (File No. 333-170425) and incorporated herein by reference).
3.4	Second Amended and Restated By-Laws (previously filed as Exhibit 3.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011 (File No. 001-35112) and incorporated herein by reference).
4.1	Specimen Common Stock Certificate (previously filed as Exhibit 4.1 to the Company's Amendment No. 4 to Registration Statement on Form S-1 filed February 22, 2011 (File No. 333-170425) and incorporated herein by reference).
4.2	Registration Rights Agreement, dated as of May 25, 2009, between the Company and the person named therein (previously filed as Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).

- 4.3 Registration Rights Agreement, dated as of September 15, 2010, between the Company and the persons named therein (previously filed as Exhibit 4.3 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 4.4 Specimen Warrant Certificate (previously filed as Exhibit 4.4 to the Company's Amendment No. 4 to Registration Statement on Form S-1 filed February 22, 2011 (File No. 333-170425) and incorporated herein by reference).
- 4.5 Form of Warrant Agreement (previously filed as Exhibit 4.5 to the Company's Amendment No. 4 to Registration Statement on Form S-1 filed February 22, 2011 (File No. 333-170425) and incorporated herein by reference).
- 4.6 Form of Warrant Certificate, dated as of June 18, 2012 (previously filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 19, 2012 (File No. 001-35112) and incorporated herein by reference).
- 4.7 Warrant Agreement, dated as of June 18, 2012, between Medgenics, Inc. and Corporate Stock Transfer, Inc., as warrant agent (previously filed as Exhibit 10.3 to the Company's Current Report on Form 8-K filed June 19, 2012 (File No. 001-35112) and incorporated herein by reference).
- 4.8 Common Stock Purchase Warrant, dated as of June 18, 2012, issued to Maxim Partners LLC (previously filed as Exhibit 10.4 to the Company's Current Report on Form 8-K filed June 19, 2012 (File No. 001-35112) and incorporated herein by reference).
- 4.9 Registration Rights Agreement, dated as of June 18, 2012, by and among Medgenics, Inc. and the investors party thereto (previously filed as Exhibit 10.5 to the Company's Current Report on Form 8-K filed June 19, 2012 (File No. 001-35112) and incorporated herein by reference).
- 4.10 Warrant Agreement, dated as of February 8, 2013, between Medgenics, Inc. and Corporate Stock Transfer, Inc. (previously filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed February 8, 2013 (File No. 001-35112) and incorporated herein by reference).
- 4.11 Form of Series 2013-A Warrant Certificate (previously filed as Exhibit 4.2 to the Company's Current Report on Form 8-K filed February 8, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.1† Medgenics, Inc. Stock Incentive Plan, as amended and restated effective March 5, 2012 (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 5, 2012 (File No. 001-35112) and incorporated herein by reference).
- 10.2† First Amendment of the Medgenics, Inc. Stock Incentive Plan (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 1, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.3† Form of Non-Qualified Stock Option Award Agreement under the Medgenics, Inc. Stock Incentive Plan (previously filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.4† Form of Restricted Stock Award Agreement under the Medgenics, Inc. Stock Incentive Plan (previously filed as Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.5† Form of Non-Qualified Stock Option Award Terms (Outside of Plan) (previously filed as Exhibit 4.7 to the Company's Registration Statement on Form S-8 filed October 15, 2013 (File No. 333-191733) and incorporated herein by reference).

- 10.6† Employment Agreement, dated as of September 13, 2013, between Medgenics, Inc. and Michael Cola (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 16, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.7† Executive Director Appointment Letter, dated as of September 13, 2013, between Medgenics, Inc. and Michael Cola (previously filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 16, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.8† Employment Agreement, dated as of September 13, 2013, between Medgenics, Inc. and John Leaman (previously filed as Exhibit 10.3 to the Company's Current Report on Form 8-K filed September 16, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.9† Employment Agreement, dated as of September 13, 2013, between Medgenics, Inc. and Garry Neil (previously filed as Exhibit 10.4 to the Company's Current Report on Form 8-K filed September 16, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.10† Separation Agreement, dated as of September 13, 2013, between Medgenics, Inc. and Andrew L. Pearlman (previously filed as Exhibit 10.5 to the Company's Current Report on Form 8-K filed September 16, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.11† Consulting Services Agreement, dated as of September 13, 2013, between Medgenics, Inc. and Andrew L. Pearlman (previously filed as Exhibit 10.6 to the Company's Current Report on Form 8-K filed September 16, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.12† Non-Executive Director Appointment Letter, dated as of September 13, 2013, between Medgenics, Inc. and Andrew L. Pearlman (previously filed as Exhibit 10.7 to the Company's Current Report on Form 8-K filed September 16, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.13† Amended and Restated Employment Agreement, dated as of June 1, 2007, between Medgenics, Inc., Medgenics Medical Israel Ltd. and Dr. Andrew Pearlman (previously filed as Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.14† First Amendment to Amended and Restated Employment Agreement, dated as of June 1, 2008, between Medgenics, Inc., Medgenics Medical Israel Ltd. and Andrew L. Pearlman (previously filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.15† Employment Agreement, effective as of July 1, 2011, between Medgenics, Inc. and Clarence L. "Butch" Dellio (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 8, 2011 (File No. 001-35112) and incorporated herein by reference).
- 10.16† First Amendment to Employment Agreement, effective as of October 13, 2011, between Medgenics, Inc. and Clarence L. "Butch" Dellio (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 17, 2011 (File No. 001-35112) and incorporated herein by reference).
- 10.17† Separation Agreement, dated as of November 27, 2013, between Medgenics, Inc. and Clarence L. Dellio (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 29, 2013 (File No. 001-35112) and incorporated herein by reference).

- 10.18† Employment Agreement, dated as of July 1, 2007, between Medgenics, Inc., Medgenics Medical Israel Ltd. and Phyllis Bellin (previously filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.19† Employment Agreement, dated as of March 18, 2007, between Medgenics Medical Israel Ltd. and Stephen Bellomo (previously filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.20† First Amendment to Employment Agreement, dated as of July 1, 2007, between Medgenics Medical Israel Ltd. and Stephen Bellomo (previously filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.21† Employment Agreement, dated as of July 8, 2012, between Medgenics, Inc. and Dr. Marvin R. Garovoy (previously filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 (File No. 001-35112) and incorporated herein by reference).
- 10.22† Separation Agreement, effective as of November 27, 2013, between Medgenics, Inc. and Marvin R. Garovoy (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed December 6, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.23† Non-Executive Director Appointment Letter, dated as of November 14, 2007, for Eugene Andrew Bauer (previously filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.24† Consulting Services Agreement, dated as of October 18, 2010, between Medgenics, Inc. and Eugene Bauer (previously filed as Exhibit 10.40 to the Company's Amendment No. 3 to Registration Statement on Form S-1 filed February 17, 2011 (File No. 333-170425) and incorporated herein by reference).
- 10.25† First Amendment to Consulting Services Agreement, dated as of April 1, 2012, between Medgenics, Inc. and Eugene A. Bauer (previously filed as Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 (File No. 001-35112) and incorporated herein by reference).
- 10.26† Non-Executive Director Appointment Letter, dated as of November 14, 2007, for Joel Stephen Kanter (previously filed as Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.27† Non-Executive Director Appointment Letter, dated as of November 14, 2007, for Stephen Devon McMurray (previously filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.28† Non-Executive Director Appointment Letter, dated as of June 6, 2011, for Isaac Blech (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 5, 2011 (File No. 001-35112) and incorporated herein by reference).
- 10.29† Medgenics, Inc. Non-Qualified Stock Option Award Terms between Medgenics, Inc. and Sol J. Barer (previously filed as Exhibit 4.7 to the Company's Registration Statement on Form S-8 filed August 1, 2012 (File No. 333-182992) and incorporated herein by reference).
- 10.30† Director Appointment Letter, dated as of August 6, 2012, between Medgenics, Inc. and Sol J. Barer (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed August 8, 2012 (File No. 001-35112) and incorporated herein by reference).

- 10.31† Non-Executive Director Appointment Letter, dated as of March 8, 2013, between Medgenics, Inc. and Joseph J. Grano, Jr. (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 14, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.32† Non-Executive Director Appointment Letter, dated as of October 16, 2013, between Medgenics, Inc. and Wilbur H. Gantz (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 18, 2013 (File No. 001-35112) and incorporated herein by reference).
- 10.33 Yissum License Agreement, dated November 23, 2005, by and between Medgenics, Inc. and Yissum Research Development Company of the Hebrew University of Jerusalem (previously filed as Exhibit 10.23 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.34 Non-Exclusive License Agreement, dated January 25, 2007, between Medgenics, Inc. and Baylor College of Medicine (previously filed as Exhibit 10.24 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.35 Addendum to Non-Exclusive License Agreement, dated as of March 16, 2009, between Medgenics, Inc. and Baylor College of Medicine (filed herewith).
- 10.36 Second Amendment to Non-Exclusive License Agreement, dated as of December 19, 2013, between Baylor College of Medicine and Medgenics Medical Israel Ltd (filed herewith).
- 10.37 License Agreement, effective as of January 31, 2011, between Medgenics, Inc. and the Regents of the University of Michigan (previously filed as Exhibit 10.25 to the Company's Amendment No. 3 to Registration Statement on Form S-1 filed February 17, 2011 (File No. 333-170425) and incorporated herein by reference).
- 10.38 Standstill and Option Agreement, dated as of October 22, 2009, between Medgenics, Inc. and Baxter Healthcare Corporation (previously filed as Exhibit 10.27 to the Company's Amendment No. 1 to Registration Statement on Form S-1 filed December 16, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.39 Amendment No. 1 to Standstill and Option Agreement, dated as of October 22, 2009, between Medgenics, Inc. and Baxter Healthcare Corporation (previously filed as Exhibit 10.27(i) to the Company's Amendment No. 1 to Registration Statement on Form S-1 filed December 16, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.40 Amendment No. 2 to Standstill and Option Agreement, dated as of December 19, 2009, between Medgenics, Inc. and Baxter Healthcare Corporation (previously filed as Exhibit 10.27(ii) to the Company's Amendment No. 1 to Registration Statement on Form S-1 filed December 16, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.41 Amendment No. 3 to Standstill and Option Agreement, dated as of October 20, 2010, between Medgenics, Inc. and Baxter Healthcare Corporation (previously filed as Exhibit 10.27(iii) to the Company's Amendment No. 1 to Registration Statement on Form S-1 filed December 16, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.42 Fourth Amendment to Standstill and Option Agreement, effective as of June 6, 2011, among Medgenics, Inc., Baxter Healthcare Corporation, Baxter Healthcare S.A. and Baxter Innovations GmbH (previously filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 6, 2011 (File No. 001-35112) and incorporated herein by reference).

- 10.43 Clinical Trials Agreement, dated as of March 18, 2010, between Medgenics Medical Israel, Ltd. and The Medical Research, Infrastructure, and Health Services Fund of the Tel Aviv Medical Center (previously filed as Exhibit 10.28 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.44 Agreement, dated as of May 1, 2010, between Medgenics Medical Israel, Ltd. and Hadasit Medical Research Services and Development Company, Ltd. (previously filed as Exhibit 10.29 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.45 Consulting Agreement, dated as of June 18, 2008, between Medgenics, Inc. and Biologics Consulting Group, Inc. (previously filed as Exhibit 10.33 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.46 Amendment No. 1 to Consulting Agreement, effective January 1, 2010, between Medgenics, Inc. and Biologics Consulting Group, Inc. (previously filed as Exhibit 10.34 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.47 Offshore Registrar Agreement, dated as of 2007, between Medgenics, Inc. and Capita Registrars (Jersey) Limited (previously filed as Exhibit 10.41 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.48 Depository Agreement, dated as of 2008, between Medgenics, Inc. and Capita IRG Trustees Limited (previously filed as Exhibit 10.45 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
- 10.49 Form of Subscription Agreement, dated as of June 18, 2012, between Medgenics, Inc. and the Subscriber named therein (previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 19, 2012 (File No. 001-35112) and incorporated herein by reference).
- 21.1 Subsidiaries of the Company (filed herewith).
- 23.1 Consent of Kost Forer Gabbay & Kasierer (Ernst & Young) (filed herewith).
- 31.1 Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
- 31.2 Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
- 32.1 Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
- 101 Interactive Data File (furnished herewith).

† Indicates a management contract or compensatory plan or arrangement contemplated by Item 15(a)(3) of Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEDGENICS, INC.

Date: February 20, 2014

By: /s/ Michael F. Cola
Michael F. Cola
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Michael F. Cola</u> Michael F. Cola	President, Chief Executive Officer and Director (Principal Executive Officer)	February 20, 2014
<u>/s/ John H. Leaman</u> John H. Leaman	Chief Financial Officer (Principal Financial Officer)	February 20, 2014
<u>/s/ Phyllis K. Bellin</u> Phyllis K. Bellin	Vice President – Administration, Corporate Secretary and Treasurer (Principal Accounting Officer)	February 20, 2014
<u>/s/ Sol J. Barer</u> Sol J. Barer	Chairman of the Board of Directors	February 20, 2014
<u>/s/ Eugene A. Bauer</u> Eugene A. Bauer	Director	February 20, 2014
<u>/s/ Isaac Blech</u> Isaac Blech	Director	February 20, 2014
<u>/s/ Alastair Clemow</u> Alastair Clemow	Director	February 20, 2014
<u>/s/ Wilbur H. Gantz</u> Wilbur H. Gantz	Director	February 20, 2014
<u>/s/ Joseph J. Grano, Jr.</u> Joseph J. Grano, Jr.	Director	February 20, 2014
<u>/s/ Joel S. Kanter</u> Joel S. Kanter	Director	February 20, 2014
<u>/s/ Stephen D. McMurray</u> Stephen D. McMurray	Director	February 20, 2014
<u>/s/ Andrew L. Pearlman</u> Andrew L. Pearlman	Director	February 20, 2014

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