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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, 2012

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	**98-0217544**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
555 California Street, Suite 365, San Francisco, CA	**94104**
(Address of Principal Executive Offices)	**(Zip Code)**

(415) 568-2245
(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 29, 2012 was $102,939,616.80.

As of March 11, 2013, the registrant had 17,997,808 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 2013 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, 2012.

MEDGENICS, INC.

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PART I

ITEM 1 - Business.

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.

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 $100+ billion protein therapeutics market. Our Biopump™ Platform Technology converts a sliver of the patient's own dermal skin tissue into a protein-producing "Biopump" to continuously produce and deliver therapeutic proteins, and when implanted under the patient's skin, has the potential to deliver several months of protein therapy from a single procedure without the need for a series of frequent injections. The proof of concept of our Biopump Platform Technology has been demonstrated using EPODURE™ producing erythropoietin (EPO) for anemia, which has shown elevation and stabilization of hemoglobin levels in anemic patients, many lasting for six or more months from a single administration in a phase I/II dose-ranging trial on chronic kidney disease (CKD) patients, with one patient experiencing elevation and stabilization of hemoglobin levels for over 36 months.

Our Biopump is a tissue micro-organ (MO) that acts as a biological pump created from a toothpick-size sliver of the patient's dermal tissue to produce and secrete a particular protein. 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 process allows us to process one or more dermis MO's outside the patient to become Biopump protein producing units in 10 – 15 days, each making a measured daily amount of a specific therapeutic protein to treat a specific chronic disease. Based on a patient's particular dosage need, we can determine how many Biopumps to then insert under the patient's skin to provide a sustained dose of protein production and delivery for several months. We believe the dosage of protein can be reduced by simple ablation or excision of inserted Biopumps or increased by the addition of more Biopumps to provide personalized dosing requirements for each patient as needs change. We believe that medical personnel will only require brief training to become proficient in using our DermaVac for harvesting and implanting, which will enable implementation of Biopump therapies by the patient's local physician. We have demonstrated that MOs and Biopumps can be processed in individual sealed chambers which can 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 15,000 Biopumps to date which have demonstrated in the laboratory the capability for sustained production of therapeutic proteins, including EPO to treat anemia, interferon-alpha (INF-α) to treat various forms of hepatitis and Factor VIII clotting protein to treat hemophilia. The *in vitro* stability and simplicity in handling of the Biopump is another key feature separating Biopump's tissue therapy approach from that of therapies based on individual cells grown in culture. Biopumps use the patient's intact tissue implanted subcutaneously where it heals in place. We believe that this facilitates location for ablation or removal if it becomes necessary to reduce dose or stop therapy. A major challenge of cell-based therapies is that protein-producing cells wander to unknown locations, making it difficult or impossible to reduce or cease therapeutic delivery. We believe that by remaining local and potentially reversible by ablation/excision, Biopumps will avoid this problem and resolve a major hurdle of gene therapy.

We believe our Biopump Platform Technology may be applied to produce an array of other therapeutic proteins from the patient's own dermal tissue in order to treat a wide range of chronic diseases or conditions. We believe our personalized approach could replace many of the existing protein therapies, which use proteins produced in animal cells administered by frequent injections over long periods of time.

Clinical proof of concept of the Biopump Platform Technology was reported in a phase I/II study using 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. We call such Biopumps EPODURE. 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 proof of concept and shown safety and efficacy of our technology so far in its first application: EPODURE for treatment of renal anemia. 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) of our IND (Investigational New Drug) application for a phase II study in the United States for EPODURE in treatment of anemia in patients on dialysis. We expect to commence the U.S. trial in the latter part of 2013. Meanwhile, we are engaged in a similar phase IIa study of EPODURE in treatment of anemia in patients on dialysis in Israel, where we have treated the first four patients. We presented early results from these dialysis patients at the November 2012 annual meeting of the American Society of Nephrology.

In a further proof of principle of our Biopump Platform Technology, in 2010 leading liver experts presented preclinical data showing months of sustained production by Biopumps of INF-α, the therapeutic protein widely used in the treatment of various forms of hepatitis, in vitro, at a major European liver conference. We call such Biopumps INFRADURE™. Several leading experts in the field of hepatitis have indicated their belief that INFRADURE has potential as a replacement for INF-α injections and their side effects not only in treatment of hepatitis C, but also in hepatitis B, hepatitis D and other indications. In November 2012, we convened a meeting of 15 hepatitis experts from the United States, Europe, Israel and Australia, including several of the key opinion leaders in hepatitis D and B, during which these experts confirmed that unmet needs in hepatitis D and B could potentially be effectively addressed by INFRADURE Biopumps. In addition, as INF-α is used in treating other diseases such as certain forms of cancer, we believe INFRADURE may have potential in some of these as well. We have obtained all necessary approvals to initiate two proposed new clinical trials of INFRADURE in Israel: a phase I/II study of INFRADURE in treatment of naïve (previously untreated) patients with hepatitis C (genotypes 2 and 3), and another phase I/II study of INFRADURE in treatment of patients with hepatitis C (genotype 1) who have relapsed from previous treatment. We recently initiated the first of such trials in Israel, to treat patients with hepatitis C genotypes 2 and 3. We are in the process of preparing an IND application to be submitted to the FDA in late 2013/early 2014 for INFRADURE to treat hepatitis B. We are also preparing an IND application for INFRADURE to treat hepatitis D, which we would plan to submit to the FDA after receiving clearance on the hepatitis B IND. Furthermore, the FDA has granted Orphan Drug Designation for the use of INFRADURE in the treatment of patients with hepatitis D, a rare form of hepatitis, Orphan Drug Designation carries multiple benefits, including the availability of grant money, certain tax credits and seven years of market exclusivity, as well as the possibility of an expedited regulatory process.

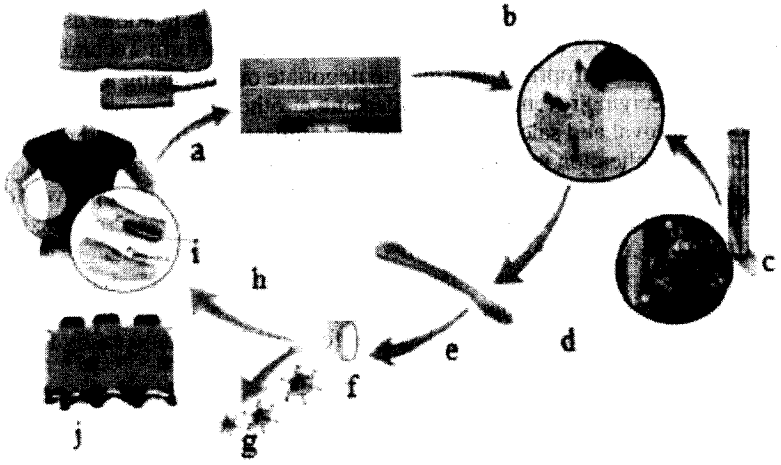
EPODURE Biopumps for the treatment of anemia have now been processed by our contract manufacturing organization (CMO) in a good manufacturing practice (GMP)-certified facility in the United States. This marks the first Biopump processing site outside of Israel, and provides us with a significant ability to scale-up our clinical and commercial capabilities to address global therapeutic areas such as anemia and hemophilia. 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 in their closed systems into fully functioning EPODURE Biopumps, meeting the release criteria for use in human clinical trials in the United States. This demonstrates our capability to support the treatment of patients at remote clinical sites, 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 to further develop this technology and to form strategic alliances and licensing agreements, along the lines of such deals being reached typically with pharmaceutical companies. We engage from time to time in discussions with a number of pharmaceutical, biotech and medical device companies to further develop our Biopump Platform Technology. We intend to further develop and leverage our core technology in order to seek multiple licensing agreements for many different proteins and clinical indications using the same core Biopump Platform Technology. Our current strategy is to take various applications of our Biopump Platform Technology through proof of basic safety and efficacy in patients (phase I/II), or further as appropriate, and then to negotiate out-licensing agreements with appropriate strategic partners. In this manner, we anticipate receiving revenues from milestone or other development or feasibility payments from such agreements in advance of regulatory approval and sales of our product candidates, while retaining control of our core technology. In addition to orphan drug designation for application in hepatitis D, we are investigating additional opportunities for the treatment of rare diseases using our Biopump Platform Technology. Rare diseases affect a small number of people worldwide. Due to the limited number of patients afflicted with one of these rare diseases, these niche applications may also offer a more expedited route to regulatory approval because pivotal clinical trials may require a smaller number of patients before regulatory agencies will consider product approval. Furthermore, many rare disease applications command substantial per-patient reimbursement levels, and thus represent attractive product opportunities even in limited target populations. In any case, 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 five years or more.

We believe that the Biopump Platform Technology has the potential to offer a better treatment alternative and replace many current methods of protein therapy, which can often involve many months of frequent injections and significant side effects. We believe that the Biopump Platform Technology provides a wide range of advantages over existing therapies and will appeal and offer benefits to doctors, patients and third-party payers (e.g., Center for Medicare and Medicaid Services (CMS) or medical insurers) including:

- potentially lower treatment costs;
- improved safety;
- reduced side effects;
- elimination of frequent injections;
- increased efficacy in chronic disease management;
- reversible treatment;
- personalized medicine;
- extended treatment to undertreated populations; and
- better 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 the patient. The DermaVac positions the skin and guides a high-speed rotating hollow core needle, providing a straightforward removal of the tissue. This procedure is intended to be performed in a physician's office under a local anesthetic. It is minimally invasive to enable rapid healing with little or no scarring.

(b) *Transfer to processing station* - after harvesting, the MOs are transferred to a Biopump processing center for processing into Biopumps.

(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 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 between one and two weeks 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 the clinic and in the laboratory, starting with the phase I/II clinical trial for our first product, the EPODURE Biopump, which was conducted in Israel under approval of the Israeli Ministry of Health in consultation with the FDA (but not under an IND application process of the FDA). 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. This stands in contrast to the longest intra-treatment period of an approved treatment for anemia, which is one month, and which has recently been recalled by FDA. The safety and efficacy data from the phase I/II study formed a major part of our IND application for a phase IIb study using EPODURE to treat anemia in dialysis patients in the United States, which was cleared by FDA in mid-2012. We believe that the study results for our first EPODURE study in patients showed that tissue Biopumps can provide safe and sustained protein therapy in patients, successfully demonstrating the Biopump concept for the first protein – erythropoietin (EPO). As a result, we are now expanding our product candidate pipeline using the same Biopump Platform Technology with continued laboratory development of Biopumps producing different proteins. We have developed in the laboratory and demonstrated in animal models our next product candidate, the INFRADURE Biopump, which produces INF-α to treat a range of diseases including various forms of hepatitis as well as other indications. We have commenced our first clinical study using INFRADURE under approval from the Israel Ministry of Health: a phase I/II study in hepatitis C, initially focusing on genotypes 2 and 3. Top experts in hepatitis have advised us that if we can demonstrate that INFRADURE provides safe and effective sustained delivery of INF-α in hepatitis C, we will likely be able to demonstrate INFRADURE's ability to treat hepatitis B and hepatitis D as well. Applying the same Biopump Platform Technology to a completely different protein and clinical indication, we have also developed and demonstrated HEMODURE™ Biopumps in the laboratory that make blood clotting Factor VIII for treating hemophilia. We believe that the EPODURE clinical results, together with the laboratory results for the INFRADURE Biopump and HEMODURE Biopump, demonstrate that our Biopump Platform Technology is capable of sustained continuous production of various therapeutic proteins.

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

Our EPODURE Biopump is designed to provide a safer, more reliable, and cost-effective anemia therapy which we believe can better maintain hemoglobin within a defined safe range while also 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, which has the effect of 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, and potentially reducing the healthcare costs of treating these patients. This supports the critical need for a more steady EPO delivery method, which the EPODURE Biopump is designed to address. We received approval from the Israel Ministry of Health to commence a phase II study in Israel of EPODURE in treatment of anemia in patients on dialysis and have treated four patients to date.

INFRADURE Biopump for the Treatment of Hepatitis and Other Indications

We are developing our INFRADURE Biopump to address the need for a patient-tolerable and cost-effective form of INF-α therapy for use in treatment of various forms of hepatitis and other applications listed in the FDA label for INF-α products. We believe that the INFRADURE Biopump can reduce side effects and promote patient compliance with treatment, while the steady delivery of INF- α in the physiological range could provide a more effective and lower cost alternative to INF-α injections, whose annual per patient cost includes approximately $35,000 for the INF-α drug and the costs of 52 weekly injections, monitoring and possible treatment of side effects. Top experts in hepatitis have indicated that INFRADURE Biopump could fulfill an unmet need for reliable interferon therapy for hepatitis D, a particularly aggressive form of hepatitis for which years of interferon therapy is the only effective treatment. While a relatively rare form of hepatitis in the U.S., hepatitis D is becoming a significant cause of death in Europe, now estimated to be killing more patients in a number of European countries than HIV AIDS.

We also believe that INFRADURE holds much promise to effectively address the key unmet need in the treatment of hepatitis B, namely to eliminate the hepatitis B virus (HBV), not just contain it. To date, years of expensive oral antiviral treatments have not eliminated the HBV. Instead these oral treatments act to contain the disease as long as the patient takes them. Once a patient stops taking the oral treatments, the disease rebounds. This requires the patient to continuously take anti-HBV drugs with mounting costs estimated at $10-12,000 per year, and associated health risks. Our advisors note that the gold standard for clearing HBV from the patient is to eliminate the hepatitis B surface antigen (HBsAg) by activating the immune system to fight it, known as sero-conversion – which is attained in only a small percentage of patients using oral antiviral agents and only after long-term use. Sero-conversion against HBV and surface antigen elimination has been reported to be improved by one-to-two years of INF-α therapy. However, today this requires the patient to endure regular weekly injections of pegylated INF-α with their associated side effects, creating a significant challenge in patient compliance to achieve reliable treatment. If a weekly treatment is missed, the effectiveness of the treatment is diminished. We believe INFRADURE has the potential to provide a much more practical and patient-compliant way to attain sero-conversion or surface antigen loss in a large proportion of patients by having the patient's own tissue produce and deliver the protein instead of using injections, whether supplemental to oral treatments, or on its own.

In addition, for the treatment of hepatitis C, we believe that INFRADURE can be part of a much lower cost alternative for treating most patients, compared to current triple therapies (INF-α, Ribavirin, and Boceprevir or Telaprevir) costing $75-85,000 per patient annually, or the newer direct acting antiviral agents now in development, which our advisors expect will cost at least as much. Weekly injections of the current longer lasting formulation of INF-α, pegylated INF-α (PEG-INF-α), used together with oral antiviral drug Ribavirin, has been shown in large clinical trials and in practical use to effectively treat most patients, particularly those with genotypes 2 or 3, but with the well-known unpleasant and often serious side effects of the injections as widely reported. We believe that INFRADURE will demonstrate that when used instead of INF-α injections, the same or better results will be obtained, but with better patient compliance and reduced side effect profile. We have produced many INFRADURE Biopumps which have demonstrated sustained production of INF-α for several months in the laboratory and have been tested in mice, which results were shown at a major European conference of hepatologists in April 2010. We recently initiated a phase I/II study in Israel of INFRADURE in treatment-naïve patients with hepatitis C of genotypes 2 and 3.

HEMODURE Biopump for the Treatment of Hemophilia

We are in early stage development of our HEMODURE Biopump producing Factor VIII to treat hemophilia. The HEMODURE Biopump represents a potential breakthrough in the treatment of hemophilia because it would be prophylactic (preventing bleeding) and thus could dramatically reduce the risk posed by bleeding in these patients. If HEMODURE Biopumps succeed in producing sufficient Factor VIII and in delivering it into these patients' circulation, it would represent a major step towards rendering the patient's life more normal and potentially provide significant cost savings for treatment of hemophiliacs, where the cost of Factor VIII injections in a typical hemophilia patient typically exceeds $100,000 per year according to the National Hemophilia Society. In October 2009, we entered into our first commercial collaboration agreement with Baxter Healthcare (Baxter) and worked with Baxter through September 2011 when our agreement to develop HEMODURE Biopumps expired. Our HEMODURE Biopumps produced active Factor VIII protein *in vitro*, as confirmed by testing using a standard assay at a major hemophilia center in Israel. We have also demonstrated initial delivery of Factor VIII into the blood circulation by implantation of HEMODURE Biopumps in SCID mice, using an approach similar to the approach we used with EPODURE and INFRADURE Biopumps. We continue to work on improving these results, and believe it will be feasible to reach sufficient sustained production rates of Factor VIII to warrant clinical testing with appropriate implantation site and method. Once target levels and a modified implantation method for Factor VIII Biopump delivery are in place, we intend to seek to commence a phase I/II clinical trial in humans.

Overall Protein Market and Current Therapeutic Treatment Platform

The worldwide market for protein therapy is forecast by RNCOS - Global Protein Therapeutic Market Analysis (Ed. 3, May 2010) to reach $132 billion in 2013. We estimate that the Biopump Platform Technology could potentially be applied to many elements of this market, starting with proteins to treat anemia (EPO) and then hepatitis (INF-α). In 2010, EPO injections to treat anemia generated revenues of $9.2 billion and INF-α injections for treatment of patients with hepatitis C and some forms of cancer generated revenues of $2.7 billion according to La Merie Business Intelligence, R&D Pipeline News, Top 30 Biologics 2010 (March 3, 2011). We have identified the anemia and various hepatitis markets as first priorities for applying the Biopump Platform Technology.

Examples of other conditions that may benefit from proteins produced and delivered by the Biopump Platform Technology are listed in the table below (although we have not currently commenced any research/clinical programs with respect to such conditions):

Condition	Protein therapy
Diabetes	Insulin, other candidates
Obesity	Various candidates
Multiple sclerosis	Interferon-beta
Arthritis	IL-1R
Cancer recovery	G-CSF
Chronic pain	IL-10
Growth failure/muscular atrophy	hGH
Wound healing	PDGF-BB

The current standard platform for protein 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 or dangerous side effects and require frequent visits either by home healthcare nurses or to the doctor's office. A treatment based on the administration of serial injections can suffer from poor patient compliance and, therefore, inadequate treatment can result.

As recombinant proteins are typically metabolized (i.e. broken down) by the body very quickly, they have a very short therapeutic life, ranging from a few minutes to a few hours. This means that, for many proteins, injections need to be taken at least once a week and often more frequently, to maintain 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 has no therapeutic effect. In order to keep protein levels in the blood above the minimum therapeutic level for as long as possible in between injections, large bolus injections are typically administered. Although this can extend the time before the protein 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. In the case of INF-α for treatment of hepatitis C and other applications, the overshoot typically causes serious flu-like symptoms with each injection, and can cause loss of white blood cells (neutropenia), depression, and other serious conditions.

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 the protein therapeutics, both in the United States and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we are targeting with our product candidates.

Many of the companies competing against us have financial and other resources substantially greater than ours. In addition, many of our 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.

Nearly all protein therapy currently utilizes recombinant protein delivered via serial bolus injections; however, there are many alternative ways to make protein and to deliver it. New ways to produce proteins are emerging, including production in plant cells, as well as generic production of off-patent proteins using more standard recombinant protein technology. However, we believe that each of these new production methods faces the same challenges of how to deliver the protein reliably in the intended therapeutic window over the required extended periods of treatment. We believe that the personal production of therapeutic protein inside a patient's body as provided by Biopump Platform Technology has distinct advantages over the development of these new production methods.

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 have been achieved through alteration of the protein 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 therapeutics, directly from established competitors using alternative protein manufacturing and delivery methods for EPO and INF-α to treat anemia and hepatitis, respectively. Additionally, many of these competitors currently manufacture, or are developing, a wide array of proteins such as G-CSF and hGH - protein therapies that we have identified as possible targets for the Biopump Platform Technology in the future.

We 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 some of the same advantages of Biopump therapy, delivering the desired genes to the patient's tissue to cause the patient to produce the desired protein in the body. Conventional direct gene therapies deliver genes directly to the circulation with the intent that they will find their way into enough cells to produce the requisite amount of protein to treat the clinical condition. Alternatively, ex-vivo cell based gene therapy removes cells from the patient, processes them to take up and become transfected by the desired gene and, then grows or amplifies the population to a large number of cells before injecting them back in the patient. Once in the patient, the cells generally tend to migrate until they find an appropriate "home" where they become attached to the surrounding tissue, or don't survive. In either case, whether via direct or via ex-vivo cell gene therapy, the amount of protein produced by the cells with the genes is difficult to predict. We believe that this process may also pose a safety risk since no reliable method has been developed to reduce or stop the production of the protein if needed. Since the cells producing the protein are typically in unknown locations, it is very difficult to stop their production of protein, so the treatment dosing is not downward adjustable or reversible.

The Biopump, in contrast, uses intact tissue at all times, so that the cells in the tissue never leave their natural matrix. Upon reimplantation, 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 in 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 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 developing rejection, in contrast to direct gene therapies. We believe that Biopumps address the key limitations of gene therapies, in knowing the dose, in the ability to increase or reduce it, and most importantly, in being able to effectively stop it if needed.

Business Strategy

Our primary strategy is to complete development of the core elements of the Biopump Platform Technology and associated key devices, and to be able to adapt them to treat different clinical indications. While this is proceeding, we intend to seek to enter into multiple licensing agreements for many different proteins and clinical indications using the same core Biopump Platform Technology. Our preferred approach is to develop the Biopump technology for a particular indication through proof of basic safety and efficacy in patients (phase I/II) or further as appropriate, and then to negotiate out-licensing agreements for the Biopump Platform Technology with appropriate strategic partners for such indication.

We are pursuing such approach with EPODURE. Our initial phase I/II trials demonstrated several months to over 36 months of sustained anemia treatment from a single administration of EPODURE Biopumps in patients with CKD and showed that an appropriate administration of EPODURE Biopumps can provide sustained anemia therapy without any EPO injections and represents an unprecedented duration from a single treatment in patients replacing many EPO injections. In the meantime, we continue to advance our clinical testing of EPODURE. We received FDA clearance for a phase II study of EPODURE for the treatment of anemia in dialysis patients with end-stage renal disease (ESRD) in the United States and are preparing to commence such trial in the second half of 2013.

The approach of first demonstrating proof of concept in patients before partnering is not our only option. We were able to successfully enter into a development and option agreement with Baxter Healthcare, a leader in the field of hemophilia, for the development of our HEMODURE Biopump producing Factor VIII for the treatment of hemophilia. Prior to entering into such agreement, we had not begun to develop our HEMODURE Biopump and had no laboratory or clinical results for such indication. However the sustained clinical results of our EPODURE Biopump, taken together with our prior production of INF-α by INFRADURE Biopumps, supported the concept of the Biopump as a platform to potentially provide safe and sustained production and delivery of therapeutic proteins such as Factor VIII on a continuous basis. This first deal, which succeeded in producing the first HEMODURE Biopumps, provided us with approximately $3.9 million in research and development participation and standstill fees. While our agreement with Baxter Healthcare expired in September 2011 without having reached all the milestones, we continue to improve HEMODURE performance. We believe the HEMODURE Biopump deal structure could provide a model for collaboration with strategic partners in completely new applications of Biopump more generally, including a funding mechanism for proving feasibility of a new Biopump application before commencement of licensing negotiations. We are exploring opportunities utilizing this model for further interest in new applications using the Biopump platform. We may thus seek additional development deals with strategic partners for other clinical indications or proteins using Biopump Platform Technology before we have reached the phase I/II clinical trial stage for such indication or protein.

We anticipate taking a somewhat different approach with our INFRADURE Biopump to treat hepatitis. We have recently launched a phase I/II trial of the INFRADURE Biopump for the treatment of hepatitis C in naïve patients with genotypes 2 and 3. This is a safety and escalating dose study whose immediate objective is to demonstrate proof of concept of the INFRADURE Biopump as a safe implantable treatment to produce and deliver INF-α in patients and that, with appropriate dose and administration, result in weeks or months of reduction in hepatitis C virus (HCV). Assuming the objective is achieved, this study would demonstrate INFRADURE as potential treatment for hepatitis C and provide key safety and dosing data for INFRADURE for use in preparing an IND application for FDA approval of phase II studies using INFRADURE in treating patients with hepatitis B and D in the United States and in Europe. We are currently planning to conduct such studies on our own. We believe we have the internal capabilities to bring INFRADURE as a treatment for hepatitis D towards product approval and sales without requiring a partner. This approach would aim to demonstrate the complete treatment and business model for the Biopump Platform Technology, while capturing the revenue stream from sales of a proprietary treatment for tens of thousands of patients with hepatitis D in the United States and Europe alone, and the millions more patients estimated worldwide.

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 where 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, California. 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 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 for commercial implementation of larger clinical indications, 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 microorgans 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 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 our proposed clinical study of EPODURE in the United States in 2013, and is capable of expansion as need grows. 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, to be processed by semi-automated processing stations which we anticipate to be ready for use in our proposed phase II EPODURE study in the United States . 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. We anticipate that this will allow a patient's physician to harvest MOs and administer the resulting Biopumps to patients locally, without requiring the patient to travel to a separate specialized center. We do not currently plan to sell Biopump devices outside of partnering agreements. It is possible that we may produce the Biopump products internally and sell them to our future strategic partners, or we may license the technology to our future strategic partners to allow them to produce the Biopump products themselves.

As the Biopump processing centers model evolves, a potential role has emerged for a supply chain partner to support logistics between clinical sites and processing centers. There may also be a role for a manufacturing partner to set up and run Biopump processing centers, which would produce Biopumps, using scaled-up cost-effective devices and methods currently under preliminary development. A completed supply chain may facilitate appropriate agreements with pharmaceutical or other commercial partners for harvesting MOs from, and administration of Biopumps to, patients in local medical centers. This model can offer pharmaceutical partners the advantages of Biopump therapy in their market applications, building on their existing infrastructure for selling injected therapeutics, while sparing them the need to establish their own Biopump processing centers.

Regulatory Strategy

Our overall regulatory strategy is aligned with our main business strategy of partnering with pharmaceutical, biotech, or medical companies to advance clinical development, request regulatory approvals, and eventually commercialize approved products. To that end, our strategy is to perform laboratory and animal feasibility studies and early clinical proof of concept (phase I/II clinical trials) to demonstrate the potential of the Biopump application. Generally, a strategic partner is sought after sufficient phase I/II data have been gathered to show proof of concept; however for some new indications, as with hemophilia, we may reach feasibility or partnering agreements at an earlier stage, even before start of preclinical development. For some applications the completion of phase I/II clinical trials would be the earliest we would seek to continue clinical development with a partner or collaborator who provides funding for the development through the product approval stage. However, we would expect partnering deals struck at phase II stage to yield substantially greater value to our company, and thus for some indications such as anemia and hepatitis B we plan to conduct our own phase II clinical trial. For other indications such as hepatitis D or some rare diseases, we could take a product candidate to final the product approval stage without a strategic partner. The general path towards 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

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 steps would be required by FDA to approve a phase II study

6. Submit IND for phase II study 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 phase II in the United States and possibly internationally

8. Complete end of phase II meeting with FDA, submit protocol, obtain FDA clearance and conduct phase III in the United States and possibly internationally

9. Submit BLA (Biologic License Application) for product sales

We are currently in step 7 outlined above for our first product candidate, EPODURE, having attained clearance from the FDA for a phase II trial of EPODURE 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. In June 2012, we successfully obtained an orphan drug designation for our INFRADURE Biopumps in the treatment of hepatitis D. The orphan drug designation may possibly allow a quicker approval timeframe, as well as smaller clinical trial enrollments. We plan to use the safety and dosing data from the phase I/II hepatitis C trial in Israel to prepare an IND application for phase II studies (step 6) in hepatitis B and in hepatitis D in the United States and elsewhere, as the INFRADURE Biopumps are the same for hepatitis C, B, or D. We will continue to evaluate and update our plans for the regulatory and clinical pathway for the INFRADURE Biopump with a view to determine whether there would be an advantage to seek regulatory approval of one of those product candidates in the United States, or possibly first in markets outside the United States, in light of the fact that hepatitis D is a relatively rare disease in the United States, but is more widespread internationally, with an estimated 15 million patients or more worldwide with the disease. In addition, we plan to identify other rare diseases with orphan designation which affect less than 10,000 people worldwide, in which the sustained therapy potentially offered by our Biopump Platform Technology could represent a major clinical advantage. According to the National Organization of Rare Diseases, there are thousands of such diseases, and we are exploring these to identify those most promising for our Biopump technology.

An initial approval of a Biopump product candidate by the FDA will help establish the safety and effectiveness of Biopumps as treatment for chronic diseases. Future regulatory approvals of Biopumps for other disease conditions will still need to prove their safety and effectiveness in a specific clinical indication, 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 off shore 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 the phase II study 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 phase II study protocol, together the scientific and clinical background, to the National Institutes of Health (NIH) Recombinant DNA Advisory Committee (RAC) for its review. RAC unanimously recommended proceeding with the proposed phase II study. We intend to submit applications for other geographical markets as well.

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

During 2003 and 2004, we undertook a phase I clinical trial using a short acting version of the Biopump producing EPO. That short acting version utilized a first generation adenoviral vector to process the micro-organs into Biopumps to produce and deliver EPO in ten anemic patients. The results of that phase I clinical trial were reported in the peer reviewed publication "Blood" (the Journal of the American Society of Hematology) in October 2005:

"The results of this study represent proof of principle that the implantation of an autologous genetically modified tissue into human dermis could significantly and safely increase the level of secreted proteins in the serum of patients. Furthermore, the secreted protein induced a physiological effect by increasing the level of the reticulocyte count. The implantation and physiologic effects were not associated with any significant side effects associated with the experimental drug." (We note that a number of the authors of such report were employees or consultants of our company and that, at that time, no regulatory authority had reviewed or approved these statements.)

The first generation adenoviral vector used in the Biopumps tested in the phase I clinical trial contained a substantial number of viral genes in addition to the gene for EPO. Consequently, the transduced cells were capable of producing not only EPO but also viral proteins, which the report published in "Blood" concluded were probably responsible for drawing the immune response against those cells thereby curtailing EPO delivery after ten to fourteen days. Having believed we proved the principle of the Biopump in the short-action phase I clinical trial, we then developed a non-immunogenic gutless (i.e. having none of its own genes) version of the adenoviral vector to produce the Biopumps which we believed was not likely to elicit an immune response in humans, and therefore, should be able to produce the therapeutic proteins over a sustained period in human patients. Utilizing the gutless adenoviral vector, we produced sustained-action Biopumps for two different applications: one producing EPO and the other producing INF-α. Each demonstrated continued protein production in the range of thousands of nanograms per day for six months *in vitro*. We used the gutless adenoviral vector to produce the Biopumps used in our completed phase I/II clinical trial in Israel of the EPODURE Biopump for the treatment of chronic renal anemia.

This phase I/II clinical trial was initially conducted at Hadassah Medical Center since September 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 is 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 will 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 system 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 phase I/II 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, and 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 hemoglobin 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. The final study report of the CKD trial should be complete by end of the first quarter of 2013. With respect to our phase I/II study in ESRD patients, the initial early data obtained in the first three patients treated showed evidence of EPO secretion and early maintenance of hemoglobin levels.

Our proposed phase II EPODURE clinical trial will seek to reproduce similar results to the phase I/II clinical trial in multiple centers (and in more patients), and further seek to test:

- reliable preparation of Biopumps processed in sealed chambers;
- demonstration of maintenance of hemoglobin within the new specified range of 9-11 g/dl for at least 4 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
- the requirement of less interventions during the specified time interval (currently planning for four-to-six month duration).

In preparation for the anticipated phase II study, we established and validated the GMP Biopumps processing facility in California, identified and taken steps to arrange for CRO and obtained the interest of an experienced nephrologist will be the lead Principal Investigator for the study. More than one major U.S. clinical site has asked to take part in the planned phase II clinical trial, with costs estimated to be in the $5-8 million range, depending on the number of patients. We currently plan to perform the phase II clinical trial on our own. However, if agreement is reached with an appropriate strategic partner, the phase II clinical trial could be conducted with such partner under that agreement. In the interim we have commenced a phase IIa study of EPODURE in dialysis patients with ESRD in Israel as our first use of EPODURE in patients with complete renal failure, and a forerunner to the U.S. phase II study. To date, four patients have been enrolled and the preliminary results look comparable to our completed CKD study.

If the proposed phase II study produces the anticipated results, we believe this would be followed by a phase III clinical trial for product candidate approval involving hundreds of patients at multiple centers which we would anticipate conducting with a commercial partner, and using a version of the automatic processor and sealed cassettes which would be similar to that intended for commercial use. Details of any phase III clinical trial will only be determined by the FDA upon review of the results of the data from our planned phase II study.

INFRADURE Biopump Clinical Trials: In Patients with Hepatitis C

Our first clinical study of INFRADURE is focused on hepatitis C study which is underway in Israel and will provide us with the initial opportunity to determine the safety and biologic activity of INFRADURE Biopumps in patients. In this study, we will be examining the ability of INFRADURE Biopumps to deliver INF-α into the patient, the levels of INF-α that are achieved in the serum and the biologic effect of the INF-α on the clearance of the hepatitis C antigen and other biologic effects.

This is a phase I/II, open label, uncontrolled, dose escalation study. The trial is being conducted in Israel at the Tel Aviv Medical Center and other sites. This study is exploratory in nature.

All eligible subjects will be implanted with autologous INFRADURE Biopump tissue intended to deliver therapeutic levels of INF-α. Subjects will be enrolled sequentially into one of three dose groups; the first dose group will include nine subjects receiving the lowest dose. We are starting with a low dose intended to deliver weekly an amount somewhat higher than the weekly injections of pegylated interferon used in standard of care. An interim safety review will be conducted in house after the first six subjects who receive the lowest dose have completed four weeks of treatment. If the safety review allows, an additional three patients may be enrolled in the low dose group.

Subsequently, four subjects will be enrolled into each of the remaining two treatment dose groups: middle dose, roughly double the low dose, and high dose at roughly three times the low dose. All subjects will be treated with dual therapy of implanted INFRADURE Biopumps delivering INF- α together with oral Ribavirin (Copegus) for up to 24 weeks following the Biopump implantation.

An additional 24-week follow-up period will be conducted to ensure each subject's safety. Outcomes to be measured will include safety, tolerability and biologic effects on viral clearance. To date, only one patient has been enrolled in the study, but has not been implanted with any Biopumps.

If we determine that this initial exploratory hepatitis C trial provides sufficient supportive evidence of INFRADURE Biopump safety and activity, we would then have supportable data from the INFRADURE hepatitis C trial to draw on in applying for IND clearance of phase II studies for INFRADURE in patients with hepatitis B and hepatitis D. Assuming the hepatitis C trial does provide the requisite data, we plan to submit to the FDA the IND application for hepatitis B. The plans for studies in each of these indications are at a preliminary phase but a general outline of our potential approach is described below.

INFRADURE for HEPATITIS B: Draft Clinical Development Plan

As discussed above, the current oral antiviral nucleoside therapies as stand-alone treatment do not effectively clear the patient of the hepatitis B virus (HBV). When HBV is truly cleared the surface antigen of HBV, HBsAg, is cleared, which is usually reached by attaining seroconversion against HBsAg. The oral drugs have a low HBsAg seroconversion rate of 0-5%. Accordingly, we are planning to examine whether the administration of INFRADURE in addition to nucleoside therapies can produce a higher rate of seroconversions or loss of the HBsAg from the circulation. A second potential use of INFRADURE in treating hepatitis B is as stand-alone monotherapy.

INFRADURE as Supplement to Nucleoside Therapy (Oral Drugs)

We anticipate that the hepatitis B program would begin with a phase II open label randomized study. We would enroll adults with chronic HBV infection and evidence of persistent disease despite nucleoside therapy. Using this approach, subjects will be maintained on their nucleoside therapy and INFRADURE Biopumps will be added to provide administration of INF-α. We would plan to test and administer two different doses of INFRADURE for 24 weeks of therapy and compare the results to adults who only received standard of care therapy. Current planning is to aim for a study of about 50 patients. If the phase II study provides positive information, we could then proceed to a phase IIb/III, randomized open label trial with a control of standard of care therapy in adults with chronic HBV infection and evidence of persistent disease despite nucleoside therapy. This study would use a longer duration of treatment. We would plan to examine the percent of subjects with no HBsAg detectable and seroconversion, as well as the percent of subjects with significant reduction in serum HBsAg, and the safety and tolerability of chronic INFRADURE administration. Assuming positive data, we would likely engage in a broader phase III study.

INFRADURE Monotherapy

We anticipate that the initial phase II would be a randomized open label, active control study in adults (around 50 patients) with chronic HBV infection and evidence of viral replication. INFRADURE Biopumps that would potentially be capable of secreting INF-α for 24 weeks would be implanted at two dose levels and the results compared to a control group receiving standard of care PEGASYS (peginterferon alfa-2a) 180 mcg/week injection. Assuming positive data showing a significant reduction in HBsAg, we would anticipate a larger phase IIb/III trial of around 300 subjects studied in a randomized open label, active control design. We would aim to enroll adults with chronic HBV infection and evidence of viral replication. Two different doses of INFRADURE would again be compared to standard of care.

In this study, a longer duration of treatment is contemplated and we would look to determine the percent of subjects with good suppression of the hepatitis B virus to a level which is considered as not clinically significant (the level of HBV DNA in the patient's serum less than 100,000 copies of viral DNA/ml of serum), the percent of subjects with normalization in liver enzymes (as measured by the liver enzyme ALT), the percent of subjects with clearance of serum HBeAg, the percent of subjects with clearance of HBsAg, and would also possibly examine liver histology for reduction in inflammation and fibrosis along with safety measurements over this longer time of exposure. Assuming positive data, a broader phase III study would be conducted. We would hope to be able to demonstrate superiority to standard of care or non-inferiority.

INFRADURE for HEPATITIS D: Draft Clinical Development Plan

Somewhat in parallel with the Hepatitis B program we are planning to study INFRADURE in Hepatitis D. It should be noted that patients with hepatitis D also have hepatitis B. In this indication, the safety data base requirement might be no more than a few hundred and even as few as 100 (pending discussion with the FDA). We plan an international multicenter approach to leverage the greater availability of patients worldwide compared to the low number in the United States.

The initial objective would be to assess the safety and biologic activity of INFRADURE Biopump treatment in hepatitis Delta virus (HDV) positive patients for a period of six months. We would start with a phase II open label, randomized, dose escalation, study in adults (around 30 patients), with chronic HDV infection and chronic inflammation on liver biopsy compatible with chronic viral hepatitis, who are either naïve to treatment, or at least six months off interferon treatment including previously relapsed responders. We would plan to study the administration of INFRADURE Biopumps for 24 weeks given in two or three dose levels and all subjects will have HDV genotype determined at baseline. HDV RNA and HBV DNA levels and hepatic enzymes would be measured at baseline and intermittently throughout the study until completion of therapy and follow-up. Outcome measures could include the proportion of subjects with undetectable HDV RNA, and evaluation of safety. Assuming positive data, we anticipate proceeding with a phase III study which would provide for a larger number of patients and longer treatment duration.

Patient recruitment is often a significant challenge for many clinical trials, and we have experienced significant difficulty to date in finding and recruiting sufficient appropriate patients for our EPODURE anemia studies in Israel. We cannot determine whether this is due to particular healthcare economics and clinical management practice in Israel, or to other factors. We hope and believe this will improve in future trials that we may conduct in Israel or elsewhere, including our current Israeli phase I/II study in hepatitis C and ongoing phase II study in dialysis patients, the anticipated phase II dialysis study in the United States and the planned phase II studies in hepatitis B and D.

Intellectual Property

Our goal is to obtain, maintain and enforce patent and trademark protection for our products, processes, methods and other proprietary technologies of the Biopump Platform Technology, and preserve our trade secrets both in the United States and in other countries. 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 elsewhere in the world.

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.

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 with 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 currently contains 42 issued and 82 pending patents. Applications for patents and other intellectual property rights capable of being registered have been, and will be, filed in certain key 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, which includes the EPODURE Biopump, the INFRADURE Biopump, the HEMODURE Biopump and production, processing, implantation and the tools designed for use in the Biopump procedure.

Many of the patent 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) and variants of Factor VIII are licensed from University of Michigan. The patent portfolio at the date of this report is comprised of the following issued and pending patents:

Type	Number	Jurisdiction	Owner/Licensee status
Issued patent	1	US	Yissum*
Issued patent	3	US	University of Michigan*
Issued patent	6	Korea, Singapore, India, Israel and Australia	Yissum*
Issued patent	2	EP	University of Michigan*
Issued patent	4	US	Medgenics
Issued patent	26	Non-US**	Medgenics
Patent application	6	US	Yissum*
Patent application	3	Non-US**	Yissum*
Patent application	5	US	University of Michigan*
Patent application	5	Non-US**	University of Michigan*
Patent application	11	US	Medgenics
Patent application	45	Non-US**	Medgenics

* licensed exclusively (within the defined scope) to us.

** Variously, Patent Co-operation Treaty signatory States, European Patent Organization member States, Peoples' Republic of China, Singapore, India, Australia, Canada, Japan, Israel and/or South Korea.

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

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. 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 the License Agreement, which was entered into on November 23, 2005. The License Agreement 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 License Agreement; and

- the expiration of the last Yissum patent licensed to us, which is expected to be approximately July 2022.

The scope of the License Agreement 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 License Agreement, we agreed to pay Yissum the following amounts:

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

1st 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.
2nd 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.
3rd 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 License Agreement provides that our total aggregate payment of royalties and sublicense fees to Yissum shall not exceed $10,000,000.

The License Agreement 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 License Agreement 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 License Agreement 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 references collaboration agreements between us and BCM dated January 25, 2006 and April 6, 2006). The license expires on the first date following the tenth anniversary of our first commercial sale of products incorporating the BCM licensed technology. After the license expires, we will have a perpetual, non-exclusive, royalty free license to the licensed BCM technology. 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 agreement 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;

(c) Staged milestone payments of $750,000 (in aggregate), of which $400,000 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 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 agreement expires upon the expiration of the last patent licensed to expire, which is expected to be approximately June 30, 2026.

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 agreement. The license agreement also requires that we reimburse University of Michigan for 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 agreement, University of Michigan would have the right to terminate the license agreement 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, 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, Israel, New Zealand, 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 business. We do not currently have trademark applications in any jurisdiction for the names 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 its 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.

Clinical trial programs generally follow a three-phase process. Typically, phase I studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease. phase I studies are conducted primarily to determine the metabolic and pharmacological action of the product candidate in humans and the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In phase II, studies are generally conducted in larger groups of patients having the target disease or condition in order to validate clinical endpoints, and to obtain preliminary data on the effectiveness of the product candidate and optimal dosing. This phase also helps determine further the safety profile of the product candidate. In phase III, large-scale clinical trials are generally conducted in patients having the target disease or condition to establish the effectiveness, and support the safety, of the product candidate.

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/II" 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 2012, the BLA application fee is $1,841,500.

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, and Priority Review.

- 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.

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 do 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. The FDA has proposed, but has not yet finalized, regulations for cGMPs for combination products. The final cGMP requirements for combination products are likely to require products comprised of a biological product and a medical device 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, 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.

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, 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 (12) 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), 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 Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 (2010), 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 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, which was significantly expanded in both the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 (2009), and in the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 (2010). 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 Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 (2010) established conclusively 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. A person who files suit 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 Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 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.

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 34 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 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 555 California Street, Suite 365, San Francisco, California 94104. We conduct our research and development activities primarily from our Israeli location in Misgav Business Park, Misgav. Our telephone number is (415) 568-2245 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 Nomination 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, 555 California Street, Suite 365, San Francisco, California 94104, 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 $15.07 million and $8.10 million for the years ended December 31, 2012 and 2011, respectively, and approximately $65.01 million for the period from inception through December 31, 2012. At December 31, 2012, we had an accumulated deficit of approximately $64.58 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 five 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, 2012, our cash and cash equivalents were approximately $6.43 million. We believe that the net proceeds of approximately $26.6 million from our registered public offering of common stock and Series 2013-A warrants completed in February 2013, plus our existing cash and cash equivalents, should be sufficient to meet our operating and capital requirements through 2014. 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 phase IIa study of EPODURE in Israel, and phase I/II study of , INFRADURE in Israel, and the continuing results of such trials;
- the level of preparations for our anticipated phase IIb study of EPODURE in the United States;
- the level of research and development investment required to develop our first product candidates, and 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 associated with milestones and royalties;
- the costs of recruiting and retaining qualified personnel;

- the time and costs involved in obtaining regulatory approvals; and
- the 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, 2012 includes a net liability of approximately $1.21 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. Of such amount, approximately $0.59 million represents amounts that would be payable to our President and Chief Executive Officer if his employment with us terminated.

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 phase I/II clinical trial with respect to our EPODURE Biopump in pre-dialysis patients and are conducting a phase IIa study in dialysis patients in Israel and preparing for a phase II study in dialysis patients in the United States. We have just recently commenced our first clinical trial for our INFRADURE Biopump, and have not received any data in connection with that trial. We have not commenced any other clinical trial for any other Biopump application. 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 large-scale clinical trials;
- difficulties related to large-scale manufacturing;
- 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 scale, 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 scale, 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 proof of concept 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 Phase IIb 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 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. 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 general 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 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 were only carried out on a small number of patients and therefore any conclusions 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, which could question the viability of the technology.

Severe side effects or complications in trials, or post-approval, could 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 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 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 product 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.

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 that 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 our product candidate for the treatment of CKD or other indications. 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 a material adverse effect on our business, financial condition and results of operations.

Potential difficulty with, and delays in, recruiting additional patients for phase I/II, phase IIa and IIb, and phase III 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. Delays in the recruitment of such patients could delay our trials and negatively impact our working capital requirements.

Potential difficulty with, and delays in, obtaining vectors necessary for conducting phase I/II, phase IIa and IIb, and phase III 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 source for the production and delivery of research grade versions of new vectors for developing new products. Such 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 are in the process of seeking additional sources, including considering our internal ability to produce the necessary vectors. 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 phase I/II clinical studies and for our current INFRADURE phase I/II clinical study, 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 product candidates.

Our ability to commercialize our technology is dependent on our ability to reach strategic licensing and other development agreements with appropriate partners, including pharmaceutical companies, biotech firms and medical device companies. If we are unable to successfully negotiate such agreements, we may not be able to continue to develop the Biopump Platform Technology 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 be able to replicate the 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 enter into collaborative relationships or strategic partnerships and/or license appropriate parts or uses of our technology in order to establish, develop and expand the distribution and international sale of our product candidates. 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, such as conflicts 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.

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 have no experience in marketing or selling pharmaceutical products, and we 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 preclinical 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, known and unknown, can adversely impact clinical trials and the ability to evaluate a product candidate's safety and efficacy, including:

- the FDA or other health regulatory authorities, or instructional review boards (IRB), do not approve a clinical trial protocol or place a clinical trial on hold;
- suitable patients do not enroll in a clinical trial in sufficient numbers or at the expected rate, for reasons such as the size of the 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 are adversely affected by trial conduct or patient withdrawal prior to completion of the trial;
- there is 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 exhibit greater than expected improvements or fewer than expected adverse events;

- third-party clinical investigators do not perform the clinical trials on the anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;

- service providers, collaborators or co-sponsors do not adequately perform their obligations in relation to the clinical trial or cause the trial to be delayed or terminated;

- we are unable to obtain a sufficient supply of manufactured clinical trial materials;

- regulatory inspections of manufacturing facilities require us or a co-sponsor to undertake corrective action or suspend the clinical trials;

- the interim results of the clinical trial are inconclusive or negative;

- the clinical trial, although approved and completed, generates 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 affect 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;

- repair, replacement, refunds, recall or seizure of our products;

- operating restrictions or 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;
- the withdrawal of the product from the market;
- the suspension or withdrawal of regulatory approvals;
- a refusal by such regulator to approve pending applications or supplements to approved applications that we or our licensees (if any) submit;
- a voluntary or mandatory recall;
- fines;
- a 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:

- the timing and receipt of marketing approvals;
- the safety and efficacy of the products;
- the emergence of equivalent or superior products;
- the cost-effectiveness of the 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 potential strategic partners. Together with such partners, we intend 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:

- the 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;

- the 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;

- the 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;

- the 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;

- the 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 that are 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, Strategic Advisory Board and other current and future members of our management and technical team, including Dr. Andrew Pearlman, our founder, President and Chief Executive Officer, Clarence "Butch" Dellio, our Chief Operating Officer, and Dr. Marvin Garovoy, our Chief Medical Officer, 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, Strategic Advisory Board members, 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 42 issued patents and 82 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.

The patent positions of the products being developed by us and our collaborators involve complex legal and factual uncertainties. As a result, we cannot assure that any patent applications filed by us, or by others under which we have rights, will result in patents being issued in the United States or foreign countries. In addition, there can be no assurance that the scope of any patent protection will be sufficient to provide us with competitive advantages, that any patents obtained by us or our collaborators will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights we or our collaborators may hold. Our competitors may 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 or similar products without legally infringing our patents. There can be no assurance 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.

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. 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.

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.

There can be no assurance 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. Additionally, 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.

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. For example, on September 16, 2011, the Leahy-Smith America Invents Act was signed into law. The Leahy-Smith America Invents Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent enforcement and defense. It is too early to determine what the effect or impact the Leahy-Smith America Invents Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We 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. As a result, development of our HEMODURE Biopump may be adversely impacted or delayed.

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 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 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 have pending applications on our contemplated marks or similar marks or in similar fields of use that are confusingly similar; or may be using our contemplated marks or similar marks. We may have to change our use of certain marks currently in use or contemplated 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 current 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 current economic conditions could also have a potentially significant negative impact on our ability to generate sufficient internal cash flows or access credit at reasonable rates to meet future operating expenses, service debt and fund capital expenditure. The continued weakness in world economies makes the strength and timing of any economic recovery uncertain, and there can be no assurance that global economic conditions will not deteriorate further.

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 $6,846,000, of grants from the Israeli Office of the Chief Scientist (OCS) and anticipate receiving an additional $203,000 of OCS grants for research and development activities conducted in 2013. 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, not to exceed, in aggregate, 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 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 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 Patient Protection and Affordable Care Act enacted in March 2010 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 will reduce Part A and Part B payments by 2% are expected to go into effect on April 1, 2013. Although we cannot predict the full effect on our business of the implementation of existing legislation such as the Patient Protection and Affordable Care Act 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 currently carry product liability insurance coverage in connection with our clinical trials 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 shareholders 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.

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 $4.25 per share to $16.43 per share during the 52-week trading period ending March 11, 2013. 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, many of which are beyond our control.

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

Our common stock is 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, 2012, there were outstanding options to purchase an aggregate of 1,959,543 shares of our common stock at exercise prices ranging from $2.49 per share to $14.50 per share, of which options to purchase 788,878 shares were exercisable as of such date. As of December 31, 2012, there were warrants outstanding to purchase 5,969,891 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 $5.98 per share, all of which were exercisable as of December 31, 2012. 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. 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, 2012, our officers and directors together controlled approximately 23.0% of our outstanding common stock on a fully diluted basis. In addition, as of December 31, 2012, our four largest stockholders other than management and the directors controlled approximately 10.3% 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 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 business occurs 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.

Israel withdrew unilaterally from the Gaza Strip and certain areas in northern Samaria in 2005. Thereafter Hamas, an Islamist terrorist group responsible for many attacks, including missile strikes against Israeli civilian targets, won the majority of the seats in the Parliament of the Palestinian Authority in January 2006 and took control of the entire Gaza Strip, by force, in June 2007. Since then, Hamas and other Palestinian movements have launched thousands of missiles from the Gaza strip into civilian targets in southern Israel. In late 2008, a sharp increase in rocket fire from Gaza on Israel's western Negev region, extending as far as 25 miles into Israeli territory and disrupting most day-to-day civilian activity in the proximity of the border with the Gaza Strip, prompted the Israeli government to launch military operations against Hamas that lasted approximately three weeks. Israel declared a unilateral ceasefire in January 2009, which substantially diminished the frequency of, but did not eliminate, Hamas rocket attacks against Israeli cities. In November 2012, following an increase in rocket attacks and hostile activity originating from the Gaza Strip, the Israeli government launched an air attack on Hamas. Rockets were fired into Israel extending as far as Tel Aviv and Jerusalem. After seven days, a ceasefire was agreed to by Israel and Hamas. Since then, rocket attacks have been significantly reduced, but not totally stopped. There can be no assurance that this period of relative calm will continue, especially in light of continuing rhetoric between Iran and Israel.

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. 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. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. 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. The civil unrest in Egypt, which borders Israel, resulted in significant changes to the country's government. In Syria, also bordering Israel, large and violent protests against the government are taking place. The ultimate effect of these developments on the political and security situation in the Middle East and on Israel's position within the region is not clear at this time.

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.

Not required.

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 555 California Street, Suite 365, San Francisco, California 94104. 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

In April 2011, we completed the initial public offering of our common stock and warrants in the United States. Following our U.S. initial public offering, our common stock and these warrants have traded, separately, on the NYSE MKT under the symbols "MDGN" and "MDGN.WS," respectively, since April 8, 2011. 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:

2011	High	Low
Second Quarter (April 8, 2011 to June 30, 2011)	$ 4.56	$ 2.85
Third Quarter (July 1, 2011 to September 30, 2011)	5.50	3.48
Fourth Quarter (October 1, 2011 to December 31, 2011)	4.83	2.08

2012	High	Low
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

Holders of Record

As of March 11, 2013, there were 381 holders of record of our common stock. We believe there are a substantially greater number of beneficial holders.

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 fourth quarter of 2012, the following securities were sold by us without registration under the Securities Act. The securities described below were deemed exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act and Regulation D thereunder. There were no underwriters employed in connection with any of these transactions. Proceeds from these equity financings were spent on general and administrative expenses, including salaries and other related costs, and research and development expenses.

Common Stock Issued Upon Exercise of Outstanding Warrants and Options

Five investors exercised warrants to purchase 19,739 shares of common stock at exercise prices of $5.32 and $5.57 per share or an aggregate exercise price of $109,467. In addition, four investors exercised warrants to purchase 53,316 shares of common stock at exercise prices of $5.32 and $5.57 per share using the cashless exercise method. Using this cashless exercise method, the investors were issued a total of 14,934 shares.

Six consultants exercised warrants to purchase 24,431 shares of common stock at exercise prices ranging from $5.57 to $7.35 per share using the cashless exercise method. Using this cashless exercise method, the consultants were issued a total of 7,941 shares.

Options and Warrants Issued

The Company granted three employees a total of 18,000 options exercisable at a price of $9.25 per share. The options have a 10 year term and vest in four equal annual tranches. The options were granted under the stock incentive plan.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6 - Selected Financial Data.

Not required.

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.

Forward Looking Statements

This Annual Report on Form 10-K contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Annual Report on Form 10-K that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe, "can," "continue," "could," "estimate," "expect," "intend," "may," "will," "plan," "project," "seek," "should" "target," "will," "would," and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors" included in Item 1A of this Annual Report on Form 10-K. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

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 $100+ billion protein therapeutics market. Our Biopump Platform Technology is designed to provide sustained protein 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 $15.07 million and $8.10 million for the years ended December 31, 2012 and 2011, respectively, and approximately $65.01million for the period from inception through December 31, 2012. As of December 31, 2012, we had an accumulated deficit of approximately $64.58 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. The agreement was extended in 2010 and 2011. 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, which we call the HEMODURE Biopump. Under the terms of the collaboration agreement, we received $3.97 million. The agreement, as extended, expired on September 30, 2011.

2011 and 2012 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 Amex. 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 share of Common stock were issued to the holders of the 2010 Debentures in November 2011 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.

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.

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, benefits, travel, and related costs 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, 2012, we incurred approximately $37.63 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 development of our two most advanced product candidates, the EPODURE Biopump and the INFRADURE Biopump, and our earlier-stage research and development projects including our HEMODURE Biopump.

The following table summarizes the percentages of our gross research and development expenses related to our two most advanced 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 January 27, 2000 (Inception) through December 31,
	2011	2012	2012
EPODURE Biopump	50%	50%	75%
INFRADURE Biopump	25%	40%	15%
HEMODURE Biopump & Other Product Candidates	25%	10%	10%

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 currently focused on developing our two most advanced product candidates, the EPODURE Biopump and the INFRADURE Biopump, as well as our HEMODURE Biopump and associated devices for implementing the platform technology.

Research and development expenses are shown net of participation by third parties. 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, 2012, we spent approximately $33.60 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 interest and amortization of beneficial conversion feature of convertible note, convertible debentures valuations, warrant valuations and interest incurred on debentures.

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

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 sub-contractors 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 $1.76 million and $0.86 million in the years ended December 31, 2012 and 2011, respectively, and $7.05 million from inception through December 31, 2012, from the OCS in development grants.

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 exercise. 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 exercise.

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 Amex. 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 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.

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.

Cash Flows

We had cash and cash equivalents of $6.43 million at December 31, 2012 and $5.0 million at December 31, 2011. The increase in our cash balance during 2012 was primarily the result of the private placement transaction completed in June 2012, proceeds from the exercise of options and warrants and grants from the Israeli OCS.

Net cash used in operating activities of $8.61 million for the year ended December 31, 2012 and $8.02 million for the year ended December 31, 2011 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 $10.12 million and $10.45 million for the years ended December 31, 2012 and 2011, respectively. 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

We expect to enter into licensing or other commercialization agreements for all or parts of applications of our Biopump Platform Technology to fund our continuing operations. If we are unable to enter into such agreements on terms acceptable to us, we will continue to incur losses from operations for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to the hiring of personnel and additional clinical trials, as we further develop the EPODURE Biopump, the INFRADURE Biopump and the HEMODURE Biopump. We expect that our general and administrative expenses will also increase as we expand our finance and administrative staff, add infrastructure, and incur additional costs related to being a public company in the United States, including investor relations programs, and increased professional fees. Our future capital requirements will depend on a number of factors, including 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.

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 $26.6 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 an additional 420,000 shares of common stock as may be necessary to cover over-allotments made in connection with the offering, which, to date, has not been exercised. The common stock and/or Series 2013-A warrants purchased under this option may be sold either together or separately in any combination to be determined by the underwriters.

Without taking into account any revenue we may receive as a result of licensing or other commercialization agreements we are pursuing, we believe that the net proceeds we received from this public offering will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through 2014. 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 five years; however, we do intend to seek licensing or other commercialization agreements similar to our agreement relating to the development of our HEMODURE Biopump. We anticipate that the funds received as a result of such agreements may be sufficient to fund our operations in the future. In the absence of additional funding or adequate funding from commercialization agreements, we expect our continuing operating losses to result in increases in our cash used in operations over the next several quarters and years.

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 near term. 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 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.

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.

Convertible Debentures

We irrevocably elected to initially and subsequently measure the convertible debentures issued in 2009 and 2010 entirely at fair value, in accordance with Accounting Standards Codification No. 825-10. As a result, we did not separate the embedded derivative instrument from the host contract and account for it as a derivative instrument. The convertible debentures were subject to remeasurement at each balance sheet date, and any change in fair value was recognized as a component of financial income (expense), net in the statements of operations. We estimated the fair value of these convertible debentures at the respective balance sheet dates using the Binomial option pricing model. We used a number of assumptions to estimate the fair value, including the remaining contractual terms of the convertible debentures, risk-free interest rates, expected dividend yield and expected volatility of the price of the underlying common stock.

During the year ended December 31, 2011, we recorded financial expense of $0.13 million to reflect the increase in the fair value of the convertible debentures. We did not record any comparable expense during the year ended December 31, 2012, as all of our convertible debentures were converted into common stock in connection with our IPO and are no longer outstanding.

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. 815-40-15-7I, 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, and the increase in the fair value of the warrants during the year ended December 31, 2012 of $2.34, 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, 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.

In 2007, we signed an agreement with Baylor College of Medicine (BCM) whereby BCM granted us a non-exclusive worldwide license to use, market, sell, lease and import certain technology (BCM technology), by way of any product process or service that incorporates, utilizes or is made with the use of the BCM technology. In consideration we agreed to pay BCM the following amounts:

- a one time, non-refundable license fee of $25,000 which was paid in 2007;
- an annual non-refundable maintenance fee of $20,000;

- a one-time milestone payment of $75,000 upon FDA clearance or equivalent of clearance for therapeutic use (as of December 31, 2012, we have not achieved FDA clearance); and
- an installment of $25,000 upon our executing any sublicenses in respect of the BCM technology.

All payments to BCM are recorded as research and development expenses. The license agreement will expire (unless terminated earlier for default or by us at our discretion) on the first day following the tenth anniversary of our first commercial sale of licensed products. After termination, we will have a perpetual, royalty free license to the BCM technology.

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, 2012, the aggregate contingent liability amounted to approximately $7.05 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 recoupable 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 2026 upon the expiration of the last to expire of the patent rights licensed. As of December 31, 2012, 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.

Subsequent Events

In January 2013, the Company issued a total of 55,000 shares of common stock to two consultants. Also in January 2013, the Company granted options to purchase 15,000 shares of common stock and 7,000 shares of restricted common stock to each of five 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. The restrictions with respect to these shares lapsed with respect to 50% of these shares the day after the grant and will lapse with respect to the remaining 50% 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 $7.25. These options and restricted common stock were granted under the stock incentive plan. Also, subsequent to the balance sheet date, the Company issued warrants to purchase 25,000 shares of common stock to a consultant in consideration of services rendered. These warrants have a 5 year term, are immediately exercisable, have an initial exercise price of $4.99 per share and include a cashless exercise feature.

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 $26.6 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 warrant to purchase up to an additional 420,000 shares of common stock as may be necessary to cover over-allotments made in connection with the offering. The common stock and/or Series 2013-A warrants purchased under this option may be sold either together or separately in any combination to be determined by the underwriters. To date, the underwriters have not exercised this option.

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.

On March 8, 2013, we announced the appointment of Joseph J. Grano, Jr. to our Board of Directors effective March 15, 2013. In connection with Mr. Grano's appointment, the Compensation Committee of our Board of Directors approved the grant to Mr. Grano of an inducement award consisting of stock options to purchase 300,000 shares of common stock, at a per share exercise price of $4.99, representing the closing price of the common stock on the NYSE MKT on March 7, 2013, subject to approval by the NYSE MKT of an additional listing application covering the issuance of the shares underlying such options. Such options have a five year term and 100,000 shares underlying such options will vest immediately upon grant and the remaining underlying shares will vest in equal installments on each of the first and second anniversaries of the effective date of Mr. Grano's appointment, subject to his continuous service through each vesting date.

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

Not required.

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ITEM 8 - Financial Statements and Supplementary Data.

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

CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2012

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the board of directors and stockholders 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, 2011 and 2012, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the years then ended and for the period from January 27, 2000 (inception date) through December 31, 2012. 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.

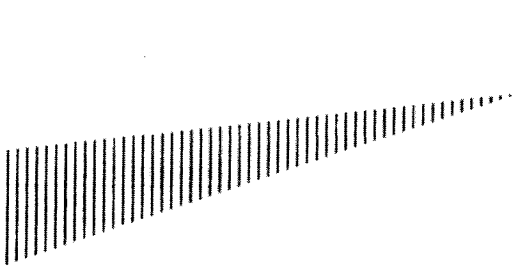
We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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, 2011 and 2012 and the consolidated results of their operations and their cash flows for each of the years then ended and for the period from January 27, 2000 (inception date) through December 31, 2012, 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, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2013, expressed an unqualified opinion thereon.

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

Haifa, Israel
March 14, 2013



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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the board of directors and stockholders 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, 2012, 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, 2012, 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, 2011 and 2012, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the years then ended and for the period from January 27, 2000 (inception date) through December 31, 2012 and our report dated March 14, 2013 expressed an unqualified opinion thereon.

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

Haifa, Israel
March 14, 2013

CONSOLIDATED BALANCE SHEETS

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

	Note	December 31, 2011	December 31, 2012
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	3	$ 4,995	$ 6,431
Accounts receivable and prepaid expenses	4	1,122	539
Total current assets		6,117	6,970
LONG-TERM ASSETS:			
Restricted lease deposits	7(c)	52	62
Severance pay fund		259	283
Total long-term assets		311	345
PROPERTY AND EQUIPMENT, NET	5	434	352
DEFERRED ISSUANCE EXPENSES	13	-	40
Total assets		$ 6,862	$ 7,707

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

CONSOLIDATED BALANCE SHEETS

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

	Note	December 31 2011	December 31 2012
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Trade payables		$ 903	$ 877
Other accounts payable and accrued expenses	6	1,156	1,473
Total current liabilities		2,059	2,350
LONG-TERM LIABILITIES:			
Accrued severance pay		1,328	1,492
Liability in respect of warrants	12	478	1,931
Total long-term liabilities		1,806	3,423
Total liabilities		3,865	5,773
COMMITMENTS AND CONTINGENCIES	7		
STOCKHOLDERS' EQUITY:	8		
Common stock - $0.0001 par value; 100,000,000 shares authorized; 9,722,725 shares and 12,307,808 shares issued and outstanding at December 31, 2011 and 2012, respectively		1	1
Additional paid-in capital		52,501	66,509
Deficit accumulated during the development stage		(49,505)	(64,576)
Total stockholders' equity		2,997	1,934
Total liabilities and stockholders' equity		$ 6,862	$ 7,707

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

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Note	Year ended December 31 2011	Year ended December 31 2012	Period from January 27, 2000 (inception) through December 31, 2012
Research and development expenses		$ 5,987	$ 7,187	$ 37,629
Less - Participation by the Office of the Chief Scientist	1(c)	(860)	(1,756)	(7,049)
U.S. Government Grant		-	-	(244)
Participation by third party	1(d)	(75)	-	(1,067)
Research and development expenses, net		5,052	5,431	29,269
General and administrative expenses		4,924	7,197	33,595
Other income:				
Excess amount of participation in research and development from third party	1(d)	-	-	(2,904)
Operating loss		(9,976)	(12,628)	(59,960)
Financial expenses	10	(214)	(2,429)	(5,310)
Financial income	10	2,097	5	360
Loss before taxes on income		(8,093)	(15,052)	(64,910)
Taxes on income	9(e)	3	19	95
Loss		$ (8,096)	$ (15,071)	$ (65,005)
Basic and diluted loss per share		$ (0.96)	$ (1.37)	
Weighted average number of shares of Common stock used in computing basic and diluted loss per share		8,447,908	11,023,881	

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 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	-	-	3,957	(*)	-	-	195	-	-	195
Issuance of Preferred stock in March and June 2001 at $58.45 per share, net	-	-	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.

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	-	-	-	-	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

(*) 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
	Shares	Amount	Shares	Amount	Shares	Amount				
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	-	-	-	-	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	-	-	-	-	-	-	-	-	(776)	(776)
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 at $2.49 per share and warrants, Net	463,358	(*)	-	-	-	-	-	-	952	-	952
Issuance of Common stock and warrants in November and December 2006 at $4.10 per share and warrants, net	476,736	(*)	-	-	-	-	-	-	1,615	-	1,615
Stock based compensation expense related to options and warrants granted to consultants and employees	-	-	-	-	-	-	-	-	1,161	-	1,161
Loss	-	-	-	-	-	-	-	-	-	(2,599)	(2,599)
Balance as of December 31, 2006	1,640,149	$ (*)	-	$ -	-	$ -	-	$ -	$ 22,452	$ (20,467)	$ 985

(*) 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, 2006	1,640,149	$ (*)	$ 22,452	$ (21,467)	$ 985
Issuance of Common stock and warrants in January 2007 at $4.10 per share and warrants, net	12,211	(*)	33	-	33
Issuance of Common stock and warrants in May, July and August 2007 at $5.74 per share and warrants, net	218,498	(*)	835	-	835
Exercise of warrants in July 2007	12,912	(*)	-	-	(*)
Issuance of Common stock to consultant in August 2007, net	3,492	(*)	(*)	-	-
Beneficial conversion feature embedded in convertible note	-	-	511	-	511
Issuance of Common stock and warrants in December 2007 at $6.65 - $7.35 per share and 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

(*) 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	Receipts on account of shares	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	Shares	Amount				
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 at $7.70 per share	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)

(*) 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	Receipts on account of shares	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	Shares	Amount				
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	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 $3.50 per share	126,285	(*)	364	-	-	364
Receipts on account of shares related to exercise of warrants in January 2011	-	-	-	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.

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' 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 2011	785,419	(*)	559	(25)	-	534
Stock based compensation related to options and warrants granted to consultants and employees	-	-	1,834	-	-	1,834
Issuance of Common stock in February 2011 at $4.38 per share to consultants	32,142	(*)	141	-	-	141
Issuance of Common stock in March 2011, net at $2.63 (GBP 1.75) per share	407,800	(*)	943	-	-	943
Issuance of Common stock in May 2011, net at $2.52 (GBP 1.75) per share	477,934	(*)	1,115	-	-	1,115
Issuance of Common stock in May 2011 at $3.43 (GBP 2.28) per share	5,502	(*)	19	-	-	19
Issuance of Common stock in August and September 2011 to consultants	39,080	(*)	164	-	-	164
Issuance of warrants in September 2011 to a consultant	-	-	36	-	-	36
Issuance of restricted Common stock in December 2011 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)

(*) 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 (deficit)
	Shares	Amount			
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 in the amount of $2,826	2,624,100	(*)	10,389	-	10,389
Issuance of Common stock upon conversion of debentures	1,410,432	(*)	5,585	-	5,585
Issuance of Common stock to a consultant at $3.67 per share	12,500	(*)	46	-	46
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	$ (49,505)	$ 2,997
Stock based compensation related to issuance of restricted common stock in January 2012	35,000	(*)	55	-	55
Issuance of Common stock to consultants at $4.84 and $8.79 per share in March and June 2012	30,000	(*)	204	-	204
Issuance of Common stock and warrants at $4.90 per unit in June 2012, net of issuance costs in the amount of $1,122	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

(*) Represents an amount lower than $1.

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,
	2011	2012	2012
CASH FLOWS FROM OPERATING ACTIVITIES:			
Loss	$ (8,096)	$ (15,071)	$ (65,005)
Adjustments to reconcile loss to net cash used in operating activities:			
Depreciation	98	145	1,226
Loss from disposal of property and equipment	-	-	330
Issuance of shares as consideration for providing security for letter of credit	-	-	16
Stock based compensation related to options, warrants, common shares and restricted shares granted to employees, directors and consultants	395	3,007	10,169
Interest and amortization of beneficial conversion feature of convertible note	-	-	759
Change in fair value of convertible debentures and warrants	(1,936)	2,336	3,978
Accrued severance pay, net	300	140	1,209
Exchange differences on a restricted lease deposit	4	(5)	(2)
Exchange differences on a long-term loan	-	-	3
Decrease (increase) in accounts receivable and prepaid expenses and deferred issuance expenses	533	543	(579)
Increase (decrease) in trade payables	764	(26)	1,481
Increase (decrease) in other accounts payable and accrued expenses	(79)	317	2,020
Net cash used in operating activities	(8,017)	(8,614)	(44,395)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(289)	(63)	(2,082)
Proceeds from disposal of property and equipment	-	-	173
Increase in restricted lease deposits	(10)	(5)	(60)
Net cash used in investing activities	$ (299)	$ (68)	$ (1,969)

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
	2011	2012	2012
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of shares and warrants, net	$ 10,389	$ 8,407	$ 42,908
Proceeds from exercise of options and warrants, net	63	1,711	2,722
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	52,795
Increase in cash and cash equivalents	2,136	1,436	6,431
Balance of cash and cash equivalents at the beginning of the period	2,859	4,995	-
Balance of cash and cash equivalents at the end of the period	$ 4,995	6,431	6,431
Supplemental disclosure of cash flow information:			
Cash paid during the period for:			
Interest	$ 49	$ -	$ 242
Taxes	$ 1	$ 50	$ 148
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
Issuance of Common stock and warrants to consultants	$ 604	$ -	$ 1,151
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

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. (formerly Biogenics 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").

On December 4, 2007 the Company's Common stock was admitted for trading on the AIM market of the London Stock Exchange ("AIM"). (see Note 8(d)21).

On April 13, 2011 the Company completed an Initial Public Offering ("IPO") of its Common stock on the NYSE MKT (formerly NYSE Amex), raising $10,389 in net proceeds. (see Note 8(d)38).

b. The Company and the Subsidiary are in the development stage. As reflected in the accompanying financial statements, the Company incurred a loss of $15,071 during the year ended December 31, 2012 and has an accumulated deficit of $64,576 as of December 31, 2012. 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 (see Note 13 - Subsequent Events), plus our existing cash and cash equivalents, should be sufficient to meet its operating and capital requirements through 2014.

c. In April 2012, the Subsidiary received approval for an additional Research and Development program from the Office of the Chief Scientist in Israel ("OCS") for the period October 2011 through September 2012. The approval allows for a grant of up to approximately $2,200 based on research and development expenses, not funded by others, of up to $4,130. To date, $1,460 has been received and $203 recorded as grants receivables.

d. On October 22, 2009, the Company signed a preclinical development and option agreement which was amended in December 2009 (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 ("FVIII") for the sustained treatment of hemophilia.

Under the terms of the Agreement, the Company was entitled to receive up to $4,100 to work exclusively with the Healthcare company for one year ended October 22, 2010 to develop a Biopump to test the feasibility of continuous production and delivery of this clotting protein.

NOTE 1:- GENERAL (CONT.)

d. (cont.)

The Company recognized income in its Statements of Operations 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.

Upon termination of the Agreement, 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.

In October 2010 and in July 2011, the Company and the Healthcare company agreed on extensions of the Agreement. During the extension periods, the Company assumed most of the funding responsibilities. Under the second extension, confirmatory studies were conducted implanting HEMODURE™ Biopumps producing FVIII in mice. The Healthcare company agreed to bear $75 of the costs of these studies. The Agreement, as extended, expired on September 30, 2011.

Through December 31, 2011, payments totaling $3,971 were received by the Company from the Healthcare company.

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 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 loans, 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.

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 operations 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	

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

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. During the years ended December 31, 2011 and 2012 and for the period from January 27, 2000 (inception) through December 31, 2012, no impairment losses have been identified.

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 value of these policies is recorded as an asset in the Company's balance sheet.

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.

As part of employment agreements, the Company 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 and 2012 and for the period from January 27, 2000 (inception) through December 31, 2012, amounted to $382, $318 and $2,198, 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, 2012, a full valuation allowance was provided by the Company.

U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

h. Income taxes (cont.)

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. No liability has been recorded as a result of ASC 740-10.

i. Accounting for stock based compensation

On January 1, 2006, the Company adopted 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. The Company estimated the fair value of stock options granted to employees and directors using the Binomial option pricing model.

In 2011 and 2012, 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
Dividend yield	0%	0%
Expected volatility	75%	77%
Risk-free interest rate	2.9%	1.7%
Suboptimal exercise factor	1.5-2	1.5
Contractual life (years)	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 employee stock options.

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

U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

i. **Accounting for stock based compensation (cont.)**

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
Dividend yield	0%	0%
Expected volatility	68%	80%
Risk-free interest rate	1.7%	1.1%
Contractual life (years)	1.1-9.7	2.4-9.9

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 considered to be outstanding during each year, in accordance with ASC 260, "*Earnings Per Share*" ("ASC 260").

In 2011 and 2012, all outstanding stock options and warrants have been excluded from the calculation of the diluted loss per Common share because all such securities were anti-dilutive for the periods presented.

k. **Research and development expenses**

All research and development expenses are charged to the Statements of Operations as incurred. Grants from the 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 relating to the HEMODURE Biopump 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 statements of operation 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.

- Milestones - upon the achievement of the specific milestone.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

l. **Grants and participation (cont.)**

- 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.

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, the United Kingdom 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.

Effective January 1, 2008, the Company adopted 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (CONT.)

n. **Fair value of financial instruments (cont.)**

The financial instruments carried at fair value on the Company's balance sheet as of December 31, 2011 and 2012 are warrants with down-round protection classified as a liability. See Note 12.

o. **Reclassifications**

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

U.S. dollars in thousands

NOTE 3:- CASH AND CASH EQUIVALENTS

	December 31,	
	2011	2012
In Dollars	$ 4,994	$ 6,255
In NIS	1	176
	$ 4,995	$ 6,431

NOTE 4:- ACCOUNTS RECEIVABLE AND PREPAID EXPENSES

	December 31,	
	2011	2012
Grant receivable from the OCS	$ 956	$ 203
Government authorities	81	83
Prepaid expenses and other	85	253
	$ 1,122	$ 539

NOTE 5:- PROPERTY AND EQUIPMENT, NET

Composition of property and equipment is as follows:

	December 31,	
	2011	2012
Cost:		
Furniture and office equipment	$ 117	$ 119
Computers and peripheral equipment	59	65
Laboratory equipment	364	413
Leasehold improvements	350	356
Total cost	890	953
Total accumulated depreciation	456	601
Depreciated cost	$ 434	$ 352

Depreciation expenses for the years ended December 31, 2011 and 2012 and for the period from January 27, 2000 (inception) through December 31, 2012 amounted to $98, $145 and $1,226, respectively.

U.S. dollars in thousands

NOTE 6:- OTHER ACCOUNTS PAYABLE AND ACCRUED EXPENSES

	December 31,	
	2011	2012
Employees and payroll accruals	$ 797	$ 1,063
Accrued expenses and others	359	410
	$ 1,156	$ 1,473

NOTE 7:- COMMITMENTS AND CONTINGENCIES

a. License agreements

1. On November 23, 2005, the Company signed a new 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 fixed installments measured by reference to investment made in the Company, as follows:

   I. 1st installment - $50 shall be paid when the cumulative investments in the Company by any third party or parties, from May 23, 2005, amount to at least $3,000.

   II. 2nd installment - Additional $150 shall be paid when the cumulative investments in the Company by any third party or parties, from May 23, 2005, amount to at least $12,000.

   III. 3rd installment - Additional $200 shall be paid when the cumulative investments in the Company by any third party or parties, from May 23, 2005, amount to at least $18,000.

   The 1st installment of $50 to Yissum was paid in 2007, the 2nd installment of $150 was paid in 2010 and the 3rd and final installment of $200 was paid in April 2011. Payments to Yissum are recorded as research and development expenses.

   (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, 2012.

NOTE 7:- COMMITMENTS AND CONTINGENCIES (CONT.)

a. License agreements (cont.)

2. Pursuant to an agreement dated January 25, 2007 between Baylor College of Medicine ("BCM") and the Company, BCM granted the Company a non-exclusive worldwide license of a certain technology (the "Subject Technology").

   The license gives the Company a non-exclusive right to use, market, sell, lease and import the Subject Technology by way of any product process or service that incorporates, utilizes or is made with the use of the Subject Technology.

   In consideration, the Company agreed to pay BCM the following amounts:

   I. a one time, non-refundable license fee of $25 which was paid in 2007;

   II. an annual non-refundable maintenance fee of $20;

   III. a one-time milestone payment of $75 upon FDA clearance or equivalent of clearance for therapeutic use. As of the balance sheet date, the Company did not achieve FDA clearance; and

   IV. an installment of $25 upon executing any sub-licenses that the Company executes in respect of the Subject Technology.

   All payments to BCM are recorded as research and development expenses. The license agreement shall expire (unless terminated earlier for default or by the Company at its discretion) on the first day following the tenth anniversary of the first commercial sale of licensed products by the Company, following which the Company shall have a perpetual, royalty free license to the Subject Technology. The Company paid to BCM $20 in each of 2011 and 2012.

3. Pursuant to an agreement entered into on February 11, 2011 (effective as of January 31, 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. The license agreement covers a portfolio of 2 issued and 3 pending patents. In consideration, the Company agreed to pay Michigan the following amounts:

   I. an initial license fee of $25 which was paid in 2011;

   II. 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 licence agreement;

   III. staged milestone payments of $750 (in aggregate), of which $400 will be recoupable against royalties;

   IV. 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;

   V. 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

   VI. patent maintenance costs.

   The exclusive worldwide license is expected to expire in 2026 upon the expiration of the last to expire of the patent rights licensed. The Company paid to Michigan patent maintenance costs of $123 and $42 in the years 2011 and 2012, respectively.

U.S. dollars in thousands

NOTE 7:- 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, 2012, the aggregate contingent liability amounted to approximately $7,049.

c. Lease Agreement

1. The facilities of the Subsidiary are rented under an operating lease agreement for a period ending December 2013 and the Subsidiary has the option to renew the lease for an additional period through December 2014. Future minimum lease commitment under the existing non-cancelable operating lease agreement is approximately $66 for 2013.

   As of December 31, 2012 the Subsidiary pledged a bank deposit which is used as a bank guarantee at an amount of $23 to secure its payments under the lease agreement.

2. The offices of the Company are rented under an operating lease agreement for a period ending June 30, 2013 and the Company has the option to renew the lease for an additional period through June 30, 2016. The Company paid a deposit of $10. Future minimum lease commitment under the existing non-cancelable operating lease agreement for 2013 is approximately $32.

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	
2013	$ 91
2014	61
2015	18
	$ 170

As of December 31, 2012, the Subsidiary paid three months lease installments in advance which amounted to $29.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 8:- STOCKHOLDERS' EQUITY

a. Common stock

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

b. Recapitalization of equity capital

According to a recapitalization agreement signed on March 30, 2006 with the requisite number of the Company's stockholders and Note providers, the convertible note and the outstanding Old Common stock, Series A Preferred shares and Series B Preferred shares were converted into Common stock. The conversion rates were as follows:

1. A total of 342,368 shares of Common stock were issued to the holders of the convertible Note upon conversion of the Note.

2. One share of Common stock was issued for 302 shares of Old Common stock.

3. One share of Common stock was issued for 11 Series A Preferred shares.

4. One share of Common stock was issued for 9 Series B Preferred shares.

As a result of the recapitalization of the equity, the Company issued a total of 282,452 shares of Common stock.

Pursuant to ASC 260-10 *"Earnings Per Share"*, the Company added the excess of the fair value of the Common stock that would have been issued pursuant to the original conversion terms of the Preferred shares over the fair value of the Common stock issued to the holders of the Preferred shares in the recapitalization in the amount of $436 to deficit accumulated during the development stage with a corresponding reduction in share capital and additional paid in capital.

c. Stock split and reverse split:

1. Based on a resolution approved by shareholders in November 22, 2007, a stock split was effectuated on December 4, 2007 such that 21.39149 shares of Common stock were given in exchange for each existing share of Common stock. In addition all existing warrants and options were automatically adjusted so that each warrant or option to purchase one share of Common stock was converted to a warrant or option to purchase 21.39149 shares of Common stock. Data regarding share and per share amounts in these financial statements has been retroactively adjusted to reflect this stock split.

2. In February 2011, the Company's Board of Directors approved a one (1) for thirty five (35) reverse split of the Company's Common stock and the number of authorized shares of the Company's Common stock was reduced from 500,000,000 to 100,000,000, effective February 14, 2011. Upon the effectiveness of the reverse stock split, thirty-five shares of Common stock of $0.0001 par value were converted and reclassified as one share of Common stock of $0.0001 par value. Accordingly, all references to number of shares, Common stock and per share data in the accompanying financial statements have been adjusted to reflect the stock split on a retroactive basis. Fractional shares created as a result of the stock split were paid in cash based on the then current market price. As a result of the rounding down effect, 166 shares of Common stock were eliminated.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

d. Issuance of shares, stock options and warrants to investors

1. In January and March 2000, the Company issued a total of 59,133 shares of Old Common stock at par value.

2. In August 2000, the Company issued 12,512 shares of Old Common stock in consideration of $500.

3. In August 2000, in respect of the earlier license agreement with Yissum, the Company issued 26,884 shares of Old Common stock at par value.

4. In January 2001, the Company issued 3,957 Series A Preferred shares in consideration of $200. The issuance costs amounted to $5.

5. On March 19, 2001, the Board of Directors authorized a 10 to 1 stock split and 1,000 to 1 stock split effected as stock dividend. In addition, the par value of each share was reduced from $0.001 to $0.0001.

6. In March and June 2001, the Company issued a total of 116,738 Series A Preferred shares in consideration of $6,998. The issuance costs amounted to $192.

7. In October 2002, the Company issued a total of 76,476 Series B Preferred shares in consideration for $5,353. The issuance costs amounted to $89.

8. In February, September and November 2003, the Company issued a total of 555 shares of Old Common stock in consideration of $0.195, upon exercise of stock options.

9. In April and May 2003, the Company issued a total of 30,485 Series B Preferred shares in consideration of $2,134. The issuance costs amounted to $97.

10. In January and February 2004, the Company issued a total of 1,316 Old shares of Common stock in consideration of $0.1 in cash upon exercise of stock options and $10 in consideration of services.

11. In March 2006, the Company issued 75,235 shares of Common stock as settlement of a debt.

12. In March 2006, as part of the recapitalization, warrants to purchase 61,117 shares of Common stock at an exercise price per share of $0.0001 with a term of 5 years were issued by the Company to existing holders of Old Common stock, Series A Preferred shares and Series B Preferred shares.

13. In March 2006, the Company issued 342,368 shares of Common stock in consideration for the conversion of a convertible loan.

14. In March, April and June 2006, the Company issued a total of 463,358 shares of Common stock and warrants to purchase 926,717 shares of Common stock at an exercise price per share of $2.49 and a term of 5 years in consideration of $1,149. These warrants include anti-dilution protection and a cashless exercise provision. The issuance costs amounted to $197.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

d. Issuance of shares, stock options and warrants to investors (cont.)

15. In November and December 2006, the Company issued a total of 476,736 shares of Common stock and warrants to purchase 595,921 shares of Common stock at an exercise price of $4.10 and a term of 5 years in consideration of $1,949. These warrants include anti-dilution protection and a cashless exercise provision. The issuance costs amounted to $334.

16. In January 2007, the Company issued a total of 12,211 shares of Common stock and warrants to purchase 15,264 shares of Common stock at an exercise price per share of $4.10 and a term of 5 years, in consideration of $50. These warrants include anti-dilution protection and a cashless exercise provision. The issuance costs amounted to $17.

17. In May, July, and August 2007, the Company issued a total of 218,498 shares of Common stock and warrants to purchase 46,711 shares of Common stock at an exercise price per share of $5.74 and a term of 5 years in consideration of $1,251. These warrants include anti-dilution protection and a cashless exercise provision. The issuance costs amounted to $416.

18. In July 2007, 12,912 warrants were exercised into 12,912 shares of Common stock. The cash consideration received was immaterial.

19. In August 2007, the Company issued 3,492 shares of Common stock at fair value of $18 to an advisor in consideration of consulting services related to the issuance of shares. The fair value of the shares was recorded as issuance costs.

20. On August 13, 2007, the Company issued a $1.05 million convertible unsecured promissory note ("Note"). In addition, the Company issued to the Note holder warrants to purchase up to 91,677 shares of Common stock at an exercise price per share of $5.74 and a term of 5 years. These warrants include anti-dilution protection and a cashless exercise provision. In respect of the Note and warrants, the Company recorded financial expenses relating to the beneficial conversion feature in accordance with the provisions of ASC 470-20, *"Debt with Conversion and Other Options"* ("ASC 470-20") (originally issued as EITF 98-5 and EITF 00-27) in the amount of $470 with a corresponding credit to additional paid in capital in shareholders' equity. The Company computed the value of the warrants using the Black-Scholes option pricing model with the following assumptions: a risk-free interest rate of 4.72%, zero dividends, volatility of 66%, and an expected term of 5 years. On November 14, 2007, the Note term was extended to December 15, 2007. In respect of this change, the Company recorded additional financial costs of $42 in the statement of operations with a corresponding credit to additional paid-in capital in shareholders' equity. On December 4, 2007, the Note was converted into 183,355 shares of Common stock.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

d. Issuance of shares, stock options and warrants to investors (cont.)

21. On December 4, 2007, the Company's Common stock was admitted for trading on the AIM Market of the London Stock Exchange (AIM). Concurrently, the Company placed 275,429 shares of Common stock at a per share price of GBP 3.50 ($7.35), issued 539,755 shares of Common stock and 88,126 shares of Common stock to investors and consultants, respectively, and issued additional 183,355 shares of Common stock resulting from the conversion of a convertible Note (see note 8(d)21), for a total gross consideration for GBP 3,276,985 ($6,719). The issuance costs amounted to $2,221. In addition, the Company issued warrants to purchase 27,745 shares of Common stock at an exercise price per share of $5.74, and additional warrants to purchase 165,701 shares of Common stock at an exercise price per share of $6.79, each with a term of 5 years. These warrants include anti-dilution protection and a cashless exercise provision.

22. In January 2008, a total of 101,723 warrants were exercised in a cashless conversion to 68,980 shares of Common stock by consultants of the Company. In addition 1,363 warrants were exercised and resulted in the issuance of 1,363 shares of Common stock. The cash consideration received was immaterial.

23. In April 2008, the Company issued a total of 4,074 shares of Common stock to an advisor in consideration of assistance with the Company's fund raising in relation to the placing of the Common stock on December 4, 2007.

24. In December 2008, 860 warrants were exercised and resulted in the issuance of 860 shares of Common stock. The cash consideration received upon exercise of the warrants was immaterial.

25. On December 17, 2008, the Company announced that it was implementing a warrant repricing program ("program") to encourage the exercise of existing warrants provided that such exercise was completed by February 13, 2009. To encourage existing warrant holders to exercise their warrants before the closing date as aforesaid, the following terms were offered:

    a) Reduced Exercise Price: $1.313/share (GBP 0.875/share) or the then current exercise price, whichever was lower;

    b) Bonus Warrants: for every one dollar ($1.00) or GBP 0.667 paid for exercise of warrants during this program, a new bonus warrant would be issued to purchase 0.1 share of Common stock (three shares of Common stock before the reverse stock split), which would be immediately exercisable for three years at an exercise price of $8.75 per share.

    The exercise price of any warrants that were not exercised before the expiration of the program reverted to the original price as stated in the warrant prior to the program.

26. Pursuant to the warrant repricing program mentioned above, during January and February 2009, 315,023 warrants were exercised and resulted in the issuance of 315,023 shares of Common stock in consideration of a reduced price of $406 and the issuance of 34,804 new warrants as a bonus. The issuance costs were $17. The bonus warrants were exercisable immediately for a period of three years from the issuance date at an exercise price of $8.75 per share. The consideration was paid partly in the year ended December 31, 2008 ($150) and the balance was paid in 2009. According to ASC 815 the benefit provided to the warrant holders from the reduction of the exercise price and the bonus warrants in the amount of $7 and $3 as of December 31, 2008 and December 31, 2009, respectively, was recorded as a dividend to the warrant holders.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

d. Issuance of shares, stock options and warrants to investors (cont.)

27. On October 6, 2009, the Company issued a total of 126,285 shares of Common stock in consideration of GBP 265,200 ($423). The issuance costs were $59.

28. In January 2010, an investor exercised warrants to purchase 6,105 share of Common stock at an exercise price of $4.10 per share, or an aggregate exercise price of $25. An additional investor exercised warrants to purchase 525 share of Common stock at an aggregate price of less than $1.

29. In a series of closings from March through June 2010, the Company issued a total of 413,302 shares of Common stock consisting of 407,800 shares of Common stock issued in March 2010 in consideration of GBP 713,650 ($1,078) with issuance costs of $135 and 5,502 shares of Common stock issued to directors of the Company in May 2010 in consideration of GBP 12,518 ($19).

30. In May 2010, the Company issued 477,934 shares of Common stock in consideration of $1,202. The issuance costs amounted to $87.

31. In August and September 2010, the Company issued 39,080 shares of Common stock in settlement of advisers' fees in relation to the Company's ongoing fundraising endeavors and consultancy advice to the Company's Board's Compensation Committee. Total compensation, measured as the grant date fair market value of the stock, amounted to $164.

32. In September 2010, several investors exercised warrants to purchase 402,307 shares of Common stock at an exercise price of $0.0175 per share, or an aggregate exercise price of $7, exercised warrants to purchase 30,559 shares at an exercise price of $4.10 per share, or an aggregate exercise price of $125, exercised warrants to purchase 0.1 share of Common stock (three shares of Common stock before the reverse stock split) at an exercise price of $8.75 per share, or an aggregate exercise price less than $1, and exercised warrants to purchase 87,405 shares of Common stock at an exercise price of $2.49 per share, or an aggregate exercise price of $218.

33. In September 2010, the purchasers of the 2010 Debentures (see Note 12) received warrants to purchase 428,571 shares of Common stock. Such warrants are immediately exercisable, have a 5-year term and have an exercise price of $4.54.

34. In October 2010, an investor exercised options to purchase 16,298 shares of Common stock at an exercise price of $1.61 per share using the cashless exercise mechanism. Using this cashless exercise method, the investor was issued 12,320 shares.

35. In the first quarter of 2011, 12 investors exercised warrants to purchase a total of 303,337 shares of Common stock at an exercise price of $2.49 per share using the cashless exercise mechanism. Using this cashless exercise method, the investors were issued 169,665 shares. In addition, four investors exercised warrants to purchase a total of 15,746 shares of Common stock at exercise prices of $0.002 and $2.49 per share, or an aggregate exercise price of $38.

36. In March 2011, unexercised warrants held by eight investors to purchase a total of 270,992 shares of Common stock expired. The aggregate value of these warrants, $636, was recorded to finance income.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

d. Issuance of shares, stock options and warrants to investors (cont.)

37. In April 2011, an investor exercised warrants to purchase 7,334 shares of Common stock at the exercise price of $2.49 per share using the cashless exercise mechanism. Using this cashless exercise method, the investor was issued 3,060 shares of Common stock.

38. On April 13, 2011 the Company completed the IPO of its Common stock on the NYSE Amex (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 approximately $10,389 in net proceeds after deducting underwriting discounts and commissions of $1,454 and other offering costs of approximately $1,372.

39. On the closing date of the IPO (April 13, 2011) 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. In addition the Company issued 5-year warrants to purchase 84,693 shares of Common stock (of which warrants to purchase 11,310 shares of Common stock were granted to placement agents) at an initial exercise price of $4.99 per share in connection with the conversion of the 2009 Debentures. 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. In November 2011, an additional 2,534 shares of Common stock were issued to compensate the 2010 Debenture holders for a minor portion of the interest which was not paid at the time of conversion.

40. In May 2011, a Director of the Company exercised warrants to purchase 60,507 shares of Common stock at an exercise price of $2.49 per share using the cashless exercise mechanism. The Director was issued 18,269 shares as a result of the warrant exercise. The Director received these warrants as an investor, prior to his appointment to the Board of Directors.

41. In August 2011, three investors exercised warrants to purchase a total of 137,517 shares of Common stock at an exercise price of $3.85 per share using the cashless exercise mechanism. Using this cashless exercise method, the investors were issued a total of 22,472 shares of Common stock.

42. In October 2011, several investors exercised warrants to purchase a total of 314,346 shares of Common stock at an exercise price of $3.85 per share using the cashless exercise mechanism. Using this cashless exercise method, the investors were issued a total of 21,684 shares.

    In addition, an investor exercised warrants to purchase 6,494 shares of Common stock at an exercise price of $3.85 per share. The cash consideration received was $25.

43. Also in October 2011, unexercised warrants held by an investor to purchase a total of 76,398 shares of Common stock expired. The aggregate value of these warrants, $50, was recorded to finance income.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

d. Issuance of shares, stock options and warrants to investors (cont.)

44. In the first quarter of 2012, unexercised warrants held by several investors to purchase a total of 34,804 shares of Common stock expired.

45. 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 approximately $8,407 in net proceeds after deducting private placement fees of $953 and other offering costs of $169.

46. In the second quarter of 2012, three investors exercised warrants to purchase 46,711 shares of Common stock at an exercise price of $5.37 per share using the cashless exercise method. Using this cashless exercise method, the investors were issued a total of 4,168 shares.

47. In the third quarter of 2012, two investors exercised warrants to purchase 107,770 shares of Common stock at exercise prices ranging from $4.99 to $5.32 per share using the cashless exercise method. Using this cashless exercise method, the investors were issued a total of 68,404 shares. An additional three investors exercised warrants to purchase 16,856 shares of Common stock at exercise prices ranging from $4.54 to $5.57 per share or an aggregate exercise price of $77. In addition, 56,900 publicly traded warrants were exercised at an exercise price of $6.00 per share or an aggregate exercise price of $341.

48. In the fourth quarter of 2012, five investors exercised warrants to purchase 19,739 shares of Common stock at exercise prices of $5.32 and $5.57 per share or an aggregate exercise price of $109. In addition, 8,370 publicly traded warrants were exercised at an exercise price of $6.00 per share or an aggregate exercise price of $50. In addition, in the fourth quarter of 2012, four investors exercised warrants to purchase 53,316 shares of Common stock at exercise prices of $5.32 and $5.57 per share using the cashless exercise method. Using this cashless exercise method, the investors were issued a total of 14,934 shares.

49. In the fourth quarter of 2012, unexercised warrants held by an investor to purchase 4,624 shares of Common stock expired. The aggregate value of these warrants, $24, was recorded to finance income.

50. See note 13(a) Subsequent Events.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

e. Issuance of stock options, warrants and restricted shares to employees and directors

1. On March 30, 2006, the Company adopted a stock incentive plan (the "stock incentive plan") according to which options to purchase up to 609,353 shares of 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 three or four years from the date of grant. Any option which is canceled or forfeited before expiration becomes available for future grants.

   On August 23, 2007, the shareholders approved an amendment to the stock incentive plan increasing the share reserve under the stock incentive plan by 776,205 shares of Common stock to a total of 1,385,558 shares of Common stock.

   In March 2012, 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 2,478,571 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 3, 2012.

2. On June 12, 2008, the Company granted to the Company's employees 91,096 options exercisable at a price of $5.11 per share. The options have a five-year term and vest in four equal annual tranches of 22,774 each. The options were granted under the stock incentive plan terms. The fair value of these options at the grant date was $0.036 per option.

3. On December 1, 2008, the Company granted to a Director of the Company 48,895 options exercisable at a price of $1.47 per share. The options have a five-year term and vest in three equal annual tranches of 16,298 each. The options were granted under the stock incentive plan terms. The fair value of these options at the grant date was $0.91 per option.

4. No options or warrants were granted to employees or directors during the year ended December 31, 2009.

5. In September 2010, the expiry date of certain warrants and options held by the Company's Chief Executive Officer was extended from March 31, 2011 to March 31, 2016, consisting of (i) warrants to purchase 905,190 shares of Common stock at an exercise price of $2.49 per share, (ii) warrants to purchase 35,922 shares of Common stock at an exercise price of $0.04 per share, and (iii) options to purchase 182,806 shares of Common stock at an exercise price of $2.49 per share. All of the other terms of these warrants and options remain the same.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

e. Issuance of stock options, warrants and restricted shares to employees and directors (cont.)

The Company accounted for the exchange of warrants and options under the provisions of ASC 718 (formerly SFAS 123(R)) as a modification. A modification to the terms of an award should be treated as an exchange of the original award for a new award with total compensation cost equal to the grant-date fair value of the original award plus the incremental value measured at the same date. Under ASC 718, the calculation of the incremental value is based on the excess of the fair value of the (modified) award based on current circumstances over the fair value of the original option measured immediately before its terms are modified based on current circumstances. That is, the original (pre-modification) award will be valued based on current assumptions, without regard to the assumptions made on the grant date. As a result of the modification, the Company recorded incremental compensation cost of $1,426 on the modification date. The fair value was estimated using Binomial model with the following weighted-average assumptions: expected stock price volatility range of 54%-77%, risk-free interest rate of 0.3%-1.7%, expected dividend yield of 0%, suboptimal exercise factor of 2 and a contractual life of the warrants and the options as defined prior the modification and subsequently.

As the modified options and warrants were already vested, the Company recorded the incremental value measured fair value of the modified award at the modification date as operating expenses. No future compensation will be recorded.

6. In September 2010, the Company granted options to purchase 28,571 shares of Common stock under the stock incentive plan at an exercise price of $8.19 per share to each of four of the Company's non-executive directors. Such options have a 10-year term and vest in equal installments over three years. The Company also granted options to purchase 12,857 shares of Common stock at an exercise price of $8.19 per share to a director who joined the Board in August 2010. Such options have a 10-year term and vest in equal installments over three years.

   The fair value of these options at the grant date was $2.03 per option.

7. In September 2010, a Director of the Company exercised warrants to purchase 28,571 shares of Common stock at an exercise price of $2.49 per share ($71 aggregate exercise price) and used the cashless exercise mechanism to exercise warrants to purchase an additional 57,147 shares. Using this cashless exercise method, the Director was issued 39,786 shares and, together with the warrants exercised for cash, he was issued a total of 68,357 shares of Common stock.

8. In September 2010, a Director of the Company exercised options to purchase 45,701 shares of Common stock at an exercise price of $2.49 per share, or an aggregate exercise price of $114.

9. In September 2010, the Company granted to the Company's employees 91,571 options exercisable at a price of $8.19 per share. The options have a 10 year term and vest in four equal annual tranches of 22,892 each. The options were granted under the stock incentive plan terms. The fair value of these options at the grant date was $2.07 per option.

   In September 2010, a Director of the Company exercised warrants to purchase 30,559 shares of Common stock and options to purchase 45,701 shares of Common stock, each having an exercise price of $2.49 per share, using the cashless exercise mechanism. The Director was issued 21,275 shares as a result of the warrant exercise and 31,817 shares as a result of the option exercise, or 53,092 shares of Common stock in total.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

e. Issuance of stock options, warrants and restricted shares to employees and directors (cont.)

10. In December 2010, a Director of the Company exercised options to purchase 91,402 shares of Common stock at an exercise price of $2.49 per share using the cashless exercise mechanism. The Director was issued 56,859 shares as a result of the option exercise.

11. In December 2010, two employees of the Company exercised warrants. One employee exercised warrants to purchase 11,429 shares of Common stock at an exercise price of $0.01645, or an aggregate exercise price of less than $1. The other employee exercised warrants to purchase 17,143 shares of Common stock at an exercise price of $2.49 per share using the cashless exercise mechanism. The employee was issued 10,664 shares as a result of the warrant exercise.

12. In December 2010, the Company granted the Executive Chairman of the Board of the Company 57,142 shares of restricted Common stock in compensation for his services in his new role as the Executive Chairman of the Board of the Company. These shares of Common stock are restricted in that they may not be disposed of and are not entitled to dividends. These restrictions were removed in relation to 14,285 shares of Common stock on October 18, 2012 and will be removed in relation to an additional 14,285 shares of Common stock on October 18, 2013 and the final 28,572 shares of Common stock on October 18, 2014. The value of these restricted shares of Common stock, $285, was based on the fair value at the grant date and is being recognized as an expense using the straight line method. The Company recorded expenses in the amount of $74 in 2012.

13. In January 2011, the Company granted options to purchase 12,857 shares of Common stock. These options were granted under the stock incentive plan, at an exercise price of $6.55 per share to each of four of the Company's non-executive directors. Such options have a 10-year term and vest in equal installments over three years. The fair value of these options at the grant date was $2.020 per option.

14. In May and June 2011, unexercised options held by two employees to purchase a total of 34,135 shares of Common stock expired.

15. In May 2011, three employees exercised options to purchase a total of 67,231 shares of Common stock at an exercise price of $2.49 per share using the cashless exercise method. The employees were issued a total of 25,159 shares as a result of the option exercises.

16. In July 2011, the Company granted an employee 40,000 options exercisable at a price of $3.64 per share. The options have a 10-year term and vest in four equal annual tranches of 10,000 each. The options were granted under the stock incentive plan terms. The fair value of these options at the grant date was $1.597 per option.

17. In September 2011, the Company granted an employee 11,429 options exercisable at $3.86 per share. The options have a 10-year term and vest in equal tranches over four years. The options were granted under the stock incentive plan terms. The fair value of these options at the grant date was $2.099 per option.

18. In September 2011, a Director of the Company exercised options to purchase 45,701 shares of Common stock at an exercise price of $2.49 per share using the cashless exercise mechanism. The Director was issued 16,197 shares of Common stock as a result of the option exercise.

U.S. dollars in thousands

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

e. **Issuance of stock options, warrants and restricted shares to employees and directors (cont.)**

19. In December 2011, the Company granted to the Company's employees 209,857 options exercisable at a price of $3.14 per share. The options have a 10 year term and vest in four equal annual tranches. The options were granted under the stock incentive plan terms. The fair value of these options at the grant date range from $1.301 to $1.597 per option.

    In addition, in December 2011, the Company granted to an employee 35,000 options exercisable at a price of $3.14 per share. The options vested immediately and have a 10 year term. These options were granted under the stock incentive plan terms. The fair value of these options at the grant date was $1.096 per option.

20. In January 2012, the Company granted 15,000 options and 7,000 shares of restricted Common stock to each of 5 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 the remaining 50% vested in January 2013, the one year anniversary of 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 $2.66. The fair value of these options at the grant date was $1.185 per option. The value of these restricted shares of Common stock, $135, was based on the fair value at the grant date. Compensation of $55 was recorded immediately and compensation of $80 will be recognized over the vesting period. These options and restricted Common stock were granted under the stock incentive plan.

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

	Year ended December 31, 2012	
Restricted shares	Outstanding	Vested
Number of restricted shares as of December 31, 2011	57,142	14,285
Granted	35,000	17,500
Number of restricted shares as of December 31, 2012	92,142	31,785

21. In April 2012, the Company granted to the Company's employees 47,254 options exercisable at a price of $5.13 per share. The options have a 10 year term and vest in four equal annual tranches. The options were granted under the stock incentive plan. The fair value of these options at the grant date was $2.366 per option.

22. In the second quarter of 2012, unexercised options held by an employee to purchase 42,783 shares of Common stock expired.

23. In the second quarter of 2012, the Chief Executive Officer of the Company transferred by gift 16,200 warrants with an exercise price of $2.49 per share to four individuals who are not immediate family.

24. In the second quarter of 2012, a Director of the Company exercised options to purchase 4,286 shares of Common stock at an exercise price of $6.55 per share or an aggregate exercise price of $28.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

e. **Issuance of stock options, warrants and restricted shares to employees and directors (cont.)**

25. In the second quarter of 2012, an employee exercised options to purchase 6,723 shares of Common stock at an exercise price of $5.47 per share using the cashless exercise method. The employee was issued 2,433 shares as a result of the option exercise.

26. In June 2012, the Company granted the Chairman of the Board of the Company 900,000 options exercisable at a price of $10.80 per share. The options have a 5 year term. 300,000 options vested immediately upon approval of the listing application by the NYSE MKT (formerly NYSE Amex) and half of the remaining 600,000 options will vest on each of June 30, 2013 and June 30, 2014. The total compensation of $3,975 will be recognized over the vesting period. The Company recorded an expense in the amount of $1,325 during the current period. These options were granted outside of the stock incentive plan.

27. In the third quarter of 2012, 11 employees exercised options to purchase 160,685 shares of Common stock at exercise prices ranging from $3.64 to $8.19 per share using the cashless exercise method. Using this cashless exercise method, the employees were issued a total of 65,678 shares.

    In July 2012, the Company granted to an employee 20,000 options exercisable at a price of $14.50 per share. The options have a 10 year term and vest in four equal annual tranches. The options were granted under the stock incentive plan. The fair value of these options at the grant date was $8.256 per option.

28. In the third quarter of 2012, a Director of the Company exercised options to purchase 48,803 shares of Common stock at an exercise price of $7.35 per share or an aggregate exercise price of $359. In addition, two Directors of the Company exercised options to purchase 115,379 shares of Common stock at an exercise price of $7.35 per share using the cashless exercise method. Such Directors were issued a total of 36,391 shares as a result of the option exercise.

29. In the third quarter of 2012, unexercised options held by two employees to purchase a total of 20,000 shares of Common stock expired.

30. In the third quarter of 2012, the Chief Executive Officer of the Company transferred by gift 6,750 warrants with an exercise price of $2.49 per share to four individuals who are not immediate family.

31. In the fourth quarter of 2012, two employees exercised options to purchase 5,840 shares of Common stock at exercise prices ranging from $7.35 to $8.19 per share using the cashless exercise method. Using this cashless exercise method, the employees were issued a total of 1,655 shares. In addition, the estate of a deceased Director of the Company exercised options to purchase 50,039 shares of Common stock at exercise prices ranging from $6.55 to $8.19 per share using the cashless exercise method. Using this cashless exercise method, the estate was issued 8,869 shares. Also in the fourth quarter, an employee exercised options to purchase 4,967 shares of Common stock at exercise prices of $3.14 and $5.62 per share or an aggregate exercise price of $26.

32. In the fourth quarter of 2012, the Company granted three employees a total of 18,000 options exercisable at a price of $9.25 per share. The options have a 10 year term and vest in four equal annual tranches. The options were granted under the stock incentive plan. The fair value of these options on the grant date was $5.075 per option.

U.S. dollars in thousands

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

e. **Issuance of stock options, warrants and restricted shares to employees and directors (cont.)**

33. Subsequent to the balance sheet date, in January 2013, the Company granted 15,000 options and 7,000 shares of restricted Common stock to each of 5 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 $7.25. These options and restricted Common stock were granted under the stock incentive plan. Also see Note 13 (b).

34. 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 price
Outstanding at January 1, 2011	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		
Gifted by the CEO to third parties	(22,950)	$ 2.49		
Outstanding at December 31, 2012	2,656,587	$ 6.04	$ 5.00	7,046
Vested and expected to vest at December 31, 2012	2,603,154	$ 5.99	$ 4.97	6,980
Exercisable at December 31, 2012	1,587,918	$ 4.51	$ 4.08	5,726

(*) Includes warrants to purchase 402,307 shares of Common stock issued to a Director and sold to an investor and exercised in 2010 (see Note 8(d)32). Also includes options to purchase 16,298 shares of Common stock issued to a former Director and exercised in 2010 (see Note 8(d)34).

The weighted average grant date fair value of options and warrants granted to employees and directors during the years ended December 31, 2012 and 2011 was $10.01 and $3.73, respectively. As of December 31, 2012, there was $3,409 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 2.2 years.

The aggregate intrinsic value represents the total intrinsic value (the difference between the Company's Common stock fair value as of December 31, 2011 and 2012 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, 2011 and 2012, respectively.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

e. **Issuance of stock options, warrants and restricted shares to employees and directors (cont.)**

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

f. **Issuance of shares, stock options and warrants to consultants**

1. On October 16, 2008, the Company granted to a consultant warrants to purchase 19,354 shares of Common stock exercisable at a price of $5.11 per share and has contractual life of 5 years. 33.3% of the warrants vested immediately at the grant date and the remaining portion of the warrants vest in two equal annual tranches of 6,451 starting from the grant date. The warrants were granted under the stock incentive plan terms. The fair value of these warrants at the grant date was $0.179 per warrant. The fair value was estimated using Binomial model with the following weighted-average assumptions: expected stock price volatility range of 62%, risk-free interest rate of 4.2%, expected dividend yield of 0% and a contractual life of the options of five years.

2. On December 1, 2008, the Company granted to a consultant warrants to purchase 67,230 shares of Common stock exercisable at a price of $6.79 per share and has contractual life of 5 years. The warrants vest immediately at the grant date. The fair value of these warrants at the grant date was $0.327 per warrant.

3. On December 7, 2009, the Company granted to a consultant options to purchase 19,354 shares of Common stock, exercisable at a price of $4.20 per share and has contractual life of 5 years. The options vest in three equal annual tranches of 6,451. The options were granted under the stock incentive plan terms. The fair value of these options at the grant date was $3.07 per warrant. The fair value was estimated using Binomial model with the following weighted-average assumptions: expected stock price volatility range of 74.9%, risk-free interest rate of 2.4%, expected dividend yield of 0% and a contractual life of the options of five years.

4. In February 2010, the Company issued 32,142 shares of Common stock as settlement of debt for services rendered to the Company by a consultant in 2009. Total compensation, measured as the grant date fair market value of the stock, amounted to $141 and was recorded as an operating expense in the statement of operations in 2009.

5. In September 2010, the Company granted a warrant to purchase 11,369 shares of Common stock at an exercise price of $3.185 per share to a consultant. Such warrant has a 5-year term and was immediately exercisable.

   The fair value of the warrant at the grant date was $3.185 per warrant.

6. In September 2010, the Company granted options to purchase 19,069 shares of Common stock at an exercise price of $8.19 per share to each of two new members of the Company's Strategic Advisory Board. Such options have a 10 year term and vest in equal installments over three years. These options were granted under the stock incentive plan terms.

   The fair value of these options at the grant date was $3.01 per option.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

f. **Issuance of shares, stock options and warrants to consultants (cont.)**

7. In September 2010, the Company issued warrants to purchase 46,071 shares of Common stock in settlement of fees in relation to the 2010 Debentures issued in 2010. These warrants were cancelled in March 2011.

8. In the first quarter of 2011, three consultants exercised warrants to purchase 68,576 shares of Common stock at exercise prices of $0.02 and $2.49 per share using the cashless exercise mechanism. Using this cashless exercise method, the consultants were issued a total of 48,939 shares.

9. In March 2011, the Company granted options to purchase 19,068 shares of Common at an exercise price of $6.65 per share to each of two new members of the Company's Strategic Advisory Board. Such options have a 10 year term and vest in equal installments over three years. These options were granted under the stock incentive plan terms. The fair value of these options at the grant date was $2.51 per option.

10. In March 2011, unexercised warrants held by a consultant to purchase 15,234 shares of Common stock expired.

11. In April 2011, the Company granted warrants to purchase 11,310 shares of Common stock at an exercise price of $4.99 per share to placement agents in settlement of fees in relation to the 2009 Debentures.

12. In April 2011, unexercised options held by a consultant to purchase 3,056 shares of Common stock expired.

13. In June and July 2011, unexercised options held by a consultant to purchase an aggregate 19,355 shares of Common stock expired.

14. In May and June 2011, three consultants exercised options to purchase a total of 85,383 shares of Common stock at an exercise price of $2.49 per share using the cashless exercise method. Using this cashless exercise method, the consultants were issued a total of 30,553 shares.

15. In July 2011, the Company issued to consultants warrants to purchase 50,000 shares of Common stock at an exercise price of $4.01 in compensation for financial advisory services.

16. In August 2011, the Company issued to a consultant warrants to purchase 150,000 shares of Common stock at an exercise price of $4.80 in compensation for financial advisory services.

17. 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 Statement of Operations.

18. In October 2011, several consultants exercised warrants to purchase a total of 29,725 shares of Common stock at an exercise price of $3.85 per share using the cashless exercise method. Using the cashless exercise method, the consultants were issued a total of 1,896 shares.

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

f. Issuance of shares, stock options and warrants to consultants (cont.)

19. In March 2012, the Company issued 15,000 shares of Common stock to a consultant. Total compensation, measured as the grant date fair market value of the stock, amounted to $73 and was recorded as an operating expense in the Statement of Operations.

20. In April 2012, the Company granted options to purchase 15,280 shares of Common stock at an exercise price of $5.13 per share to a consultant. The options have a 10 year term and vest in four equal annual tranches. The options were granted under the stock incentive plan.

21. In the second quarter of 2012, four consultants exercised warrants to purchase 10,943 shares of Common stock at an exercise prices ranging from$4.99 to $5.37 per share using the cashless exercise method. Using this cashless exercise method, the consultants were issued a total of 2,905 shares.

22. In June 2012, the Company granted options to purchase 25,000 shares of Common stock at an exercise price of $6.86 per share to each of two consultants. The options have a 10 year term and vest in three equal annual tranches. The options were granted under the stock incentive plan. In addition, in June 2012, the Company issued 194,473 warrants to the placement agent for its June 2012 private placement. See note 8 (d)45.

23. In June 2012, the Company issued 15,000 shares of Common stock to a consultant. Total compensation, measured as the grant date fair market value of the stock, amounted to $131 and was recorded as an operating expense in the Statement of Operations.

24. In July 2012, the Company granted options to purchase 5,646 shares of Common stock at an exercise price of $14.50 per share to each of two consultants. The options have a 10 year term and vest in three equal annual tranches. The options were granted under the stock incentive plan.

25. In the third quarter of 2012, nine consultants exercised warrants to purchase 55,449 shares of Common stock at exercise prices ranging from $5.15 to $5.57 per share using the cashless exercise method. Using this cashless exercise method, the consultants were issued a total of 34,448 shares. In addition, a consultant exercised warrants to purchase 150,000 shares of Common stock at an exercise price of $4.80 per share or an aggregate exercise price of $720. Also in the third quarter, four consultants exercised options to purchase 35,898 shares of Common stock at exercise prices ranging from $6.65 to $7.35 per share using the cashless exercise method. Using this cashless exercise method, the consultants were issued a total of 12,839 shares.

26. In September 2012, the Company granted warrants to purchase 7,000 shares of Common stock at an exercise price of $11.16 per share to a consultant. The warrants have a five year term and vested immediately at the grant date. The fair value of these warrants at the grant date was $6.829 per warrant.

27. In the third quarter of 2012, unexercised warrants held by several consultants to purchase a total of 2,965 shares of Common stock expired.

U.S. dollars in thousands

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

f. **Issuance of shares, stock options and warrants to consultants (cont.)**

28. In the fourth quarter of 2012, seven consultants exercised options and warrants to purchase 40,934 shares of Common stock at exercise prices ranging from $5.32 to $7.35 per share using the cashless exercise method. Using this cashless exercise method, the consultants were issued a total of 12,704 shares.

29. In the fourth quarter of 2012, unexercised warrants held by a consultant to purchase 290 shares of Common stock expired.

30. Subsequent to the balance sheet date, in January 2013, the Company issued a total of 55,000 shares of Common stock to two consultants. Also subsequent to the balance sheet date, the Company issued warrants to purchase 25,000 shares of Common stock to a consultant in consideration of services rendered. These warrants have a 5 year term, are immediately exercisable, have an initial exercise price of $4.99 per share and include a cashless exercise feature.

31. 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 January 1, 2011	558,292	$ 5.04		
Granted	249,446	$ 4.93		
Exercised	(183,684)	$ 2.25		
Forfeited	(83,716)	$ 6.46		
Outstanding at December 31, 2011	540,338	$ 5.49	3.72	$ -
Granted	278,045	$ 8.80		
Expired	(3,255)	$ 5.34		
Exercised	(293,224)	$ 5.43		
Outstanding at December 31, 2012	521,904	$ 7.29	$ 4.81	$ 548
Exercisable at December 31, 2012	419,908	$ 7.22	$ 3.78	$ 474

The weighted-average grant-date fair value of warrants and options granted to consultants during the years ended December 31, 2011 and 2012 was $2.80 and $5.35, respectively. As of December 31, 2012, there was $495 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted to consultants under the Company's stock incentive plan. That cost is expected to be recognized over a weighted-average period of 1.2 years.

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

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

g. Compensation expenses

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

	Year ended December 31,	
	2011	2012
Research and development expenses	$ 78	$ 225
General and administrative expenses	317	2,782
	$ 395	$ 3,007

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

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

h. Summary of options and warrants:

A summary of all the options and warrants outstanding as of December 31, 2011 and 2012 is presented in the following tables:

	As of December 31, 2011			
Options / Warrants	Exercise Price per Share ($)	Options and Warrants Outstanding	Options and Warrants Exercisable	Weighted Average Remaining Contractual Terms (in years)
Options:				
Granted to Employees and Directors	2.49	182,806	182,806	4.3
	3.14	244,857	35,000	9.9
	3.64	40,000	-	9.5
	3.86	11,429	-	9.7
	4.10	42,783	42,783	0.6
	5.40	49,536	37,152	1.4
	6.55	51,428	-	9.0
	7.35	332,046	332,046	0.9
	8.19	218,713	65,273	8.7
		1,173,598	695,060	
Granted to Consultants	4.20	19,354	12,903	2.9
	5.40	19,354	19,354	1.8
	6.65	38,136	12,712	8.9
	7.35	46,045	46,045	0.9
	8.19	38,136	12,712	8.7
		161,025	103,726	
Total Options		1,334,623	798,786	
Warrants:				
Granted to Employees and Directors	2.49	905,190	905,190	4.3
Granted to Consultants	3.19	11,370	11,370	3.7
	4.01	50,000	50,000	4.5
	4.80	150,000	150,000	4.6
	4.99	11,310	11,310	4.3
	5.15	16,976	16,976	0.9
	5.37	37,508	37,508	0.7
	5.65	102,149	102,149	1.6
		379,313	379,313	
Granted to Investors	0.0002	35,922	35,922	4.3
	4.54	428,571	428,571	3.7
	4.99	73,383	73,383	4.3
	5.37	166,132	166,132	0.7
	5.65	50,721	50,721	0.9
	6.00	2,829,000	2,829,000	4.3
	8.75	34,804	34,804	0.1
		3,618,533	3,618,533	
Total Warrants		4,903,036	4,903,036	
Total Options and Warrants		6,237,659	5,701,822	

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

NOTE 8:- STOCKHOLDERS' EQUITY (CONT.)

h. Summary of options and warrants (cont.):

Options / Warrants	As of December 31, 2012			
	Exercise Price per Share ($)	Options and Warrants Outstanding	Options and Warrants Exercisable	Weighted Average Remaining Contractual Terms (in years)
Options:				
Granted to Employees and Directors	2.49	182,806	182,806	3.3
	2.66	75,000	-	9.0
	3.14	244,143	86,750	8.9
	3.64	35,700	5,700	8.5
	3.86	11,429	2,857	8.7
	5.13	47,254	-	9.3
	5.66	23,280	23,280	0.5
	6.55	42,856	8,572	8.0
	8.19	173,879	95,713	7.7
	9.25	18,000	-	9.8
	10.80	900,000	300,000	4.5
	14.50	20,000	-	9.5
		1,774,347	705,678	
Granted to Consultants				
	4.20	19,354	19,354	1.9
	5.13	15,280	-	9.3
	5.66	19,354	19,354	0.8
	6.65	31,780	19,068	8.0
	6.86	50,000	-	9.5
	8.19	38,136	25,424	7.7
	14.50	11,292	-	9.5
		185,196	83,200	
Total Options		1,959,543	788,878	
Warrants:				
Granted to Employees and Directors	2.49	882,240	882,240	3.3
Granted to Consultants	3.19	11,370	11,370	2.7
	4.01	50,000	50,000	3.5
	4.99	6,635	6,635	3.3
	5.57	67,230	67,230	0.9
	9.17	194,473	194,473	4.5
	11.16	7,000	7,000	4.5
		336,708	336,708	
Granted to Investors	0.0002	35,922	35,922	3.3
	2.49	22,950	22,950	3.3
	4.54	412,500	412,500	2.7
	4.99	57,291	57,291	3.3
	6.00	2,763,730	2,763,730	3.3
	8.34	1,458,550	1,458,550	4.5
		4,750,943	4,750,943	
Total Warrants		5,969,891	5,969,891	
Total Options and Warrants		7,929,434	6,758,769	

NOTE 9:- 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 Ordinance and the Income Tax (Inflationary Adjustments) Law, 1985: (the "law").

   Results of the Subsidiary for tax purposes are measured and reflected in nominal NIS. The financial statements are presented in U.S. dollars.

   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 (or paragraph 9(f) of FAS 109), 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.

   Programs, whose year of election entitled them to a beneficiary enterprise status, are required, among others, to make a minimum qualifying investment in productive assets such as machinery and equipment, which must be carried out within three years. The minimum qualifying investment for the Subsidiary is NIS 300, linked to the Israeli CPI. Productive assets that are used by the program but not owned by it will also be viewed as productive assets.

   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 and the first year the Subsidiary earns taxable income provided that 12 years have not passed since the beginning of the year of election and 14 years 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 Subsidiary policy is not to distribute a dividend as above.

NOTE 9:- TAXES ON INCOME (CONT.)

a. Tax laws applicable to the Company and the Subsidiary (Cont.)

3. The Law for the Encouragement of Capital Investments, 1959 (Cont.)

As for industrial enterprises, in each tax year during the benefit period, one of the following conditions must be met:

1. The industrial enterprise's main field of activity is biotechnology or nanotechnology as approved by the Head of the Administration of Industrial Research and Development, prior to the approval of the relevant program.

2. The industrial enterprise's sales revenues in a specific market during the tax year do not exceed 75% of its total sales for that tax year. A "market" is defined as a separate country or customs territory.

3. At least 25% of the industrial enterprise's overall revenues during the tax year were generated from the enterprise's sales in a specific market with a population of at least 12 million.

Accelerated depreciation:

The Subsidiary is eligible for deduction of accelerated depreciation on machinery and equipment used by the beneficiary enterprise at a rate of 200% from the first year of the asset's operation.

Conditions for the entitlement to the benefits:

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.

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.

On December 5, 2011, the Israeli Parliament (the Knesset) passed the Law for Tax Burden Reform (Legislative Amendments), 2011 (the "TBR Law") which, among others, cancels effective from 2012, the scheduled progressive reduction in the corporate tax rate. The TBR Law also increased the corporate tax rate to 25% in 2012. In view of this increase in the corporate tax rate to 25% in 2012, the real capital gains tax rate and the real betterment tax rate were also increased accordingly.

The effect of the abovementioned changes did not have an effect on the net deferred tax asset.

NOTE 9:- TAXES ON INCOME (CONT.)

b. Tax rates applicable to the Company and the Subsidiary (Cont.)

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, 2012, the Company had U.S. federal net operating loss carryforward for income tax purposes in the amount of approximately $36,000. 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 2032. As of December 31, 2012 the Company had net operating loss carryforward for state franchise tax purposes of approximately $34,500 which can be carried forward and offset against taxable income for 10-20 years, expiring between 2012 and 2032.

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 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, 2012, in the amount of approximately $13,600, 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 operations:

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

U.S. dollars in thousands

NOTE 9:- 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,	
	2011	2012
Deferred tax assets:		
Net operating loss carryforward	$ 9,413	$ 13,190
Allowances and reserves	305	526
Total deferred tax assets before valuation allowance	9,718	13,716
Valuation allowance	(9,718)	(13,716)
Net deferred tax asset	$ -	$ -

As of December 31, 2012, 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 its 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 and 2012, the main reconciling item of the statutory tax rate of the Company and the Subsidiary (24% to 35% in 2011 and 25% to 35% in 2012) to the effective tax rate (0%) is tax loss carryforwards and other deferred tax assets for which a full valuation allowance was provided.

U.S. dollars in thousands

NOTE 10:- FINANCIAL INCOME (EXPENSE)

	Year ended December 31,		Period from January 27, 2000 (inception) through December 31, 2012
	2011	2012	
Financial income (expense), net:			
Financial income:			
Foreign currency remeasurement adjustments	$ 28	$ -	$ 85
Warrant valuation	2,061	-	-
Interest on cash equivalents, short-term bank deposits and others	8	5	226
Others	-	-	49
	2,097	5	360
Financial expenses:			
Bank charges	(17)	(14)	(103)
Interest expenses	(71)	-	(380)
Interest and amortization of beneficial conversion feature of convertible note	-	-	(759)
Warrant valuation	-	(2,336)	(1,931)
Convertible debentures valuation	(125)	-	(2,040)
Foreign currency remeasurement adjustments	-	(76)	(76)
Others	(1)	(3)	(21)
	(214)	(2,429)	(5,310)
	$ 1,883	$ (2,424)	$ (4,950)

U.S. dollars in thousands

NOTE 11:- 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
	$ 62	$ 232	$ -	$ 294

	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

(*) Deceased

(1) Represents the fair value of options to purchase 12,857 shares of Common stock under our 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 under our stock incentive plan at an exercise price of $10.80 per share. Such options have a 10-year term and vest in equal installments over three years.
(4) Represents the fair value of options to purchase 15,000 shares of Common stock under our 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.

U.S. dollars in thousands

NOTE 12:- 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 the 2010 Convertible Debentures as a liability at their fair value according to ASC 815-40-15-7I. The liability in respect of these warrants will be remeasured at each reporting period until exercised or expired. Changes in the fair value of these warrants are reported in the statements of operations as financial income or expense.

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

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

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 January 1, 2011	$ 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	(2,061)
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	2,336
Balance as of December 31, 2012	$ 1,931

NOTE 13:- SUBSEQUENT EVENTS

a. Subsequent to the Balance Sheet date, on February 13, 2013, the Company closed 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, each consisting of one share of Common stock and a warrant to purchase one-half of a share of Common stock, at a price to the public of $5.25 per fixed combination. The warrants are currently exercisable, have an initial exercise price of $6.78 per share and expire on February 13, 2018. Gross proceeds were $29,400 or approximately $26,600 in net proceeds after deducting underwriting discounts and commissions of $2,352 and other offering costs of approximately $448. The Company 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 additional warrants to purchase up to an aggregate of 420,000 shares of Common stock. To date, the underwriters have not exercised this option. As of December 31, 2012, fundraising expenses related to this public offering of $40 have been deferred.

b. Subsequent to the Balance Sheet date, on March 8, 2013, the Company announced the appointment of a new member of the Board of Directors effective March 15, 2013. In connection with the appointment, the new board member was granted an inducement award consisting of stock options covering up to 300,000 shares of the Company's common stock, at a per share exercise price of $4.99. Such options have a five year term and 100,000 shares underlying such options will vest immediately upon the effective date of his appointment (subject to approval by the NYSE MKT of an additional listing application with respect to such options) and the remaining underlying shares will vest equally on each of the first and second anniversaries of the effective date of the appointment, subject to continuous service through each vesting date. This award was granted pursuant to a stand-alone award agreement outside of the stock incentive plan.

c. Also see Notes 8(e)33 and 8(f)30.

* * * * * * * * * * * * * * * * * * *

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, 2012, 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. 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, 2012. 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, 2012, 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, 2012 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 2013.

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 2013.

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 2013.

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 2013.

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 2013.

PART IV

ITEM 15 - Exhibits and Financial Statement Schedules.

(a)(1) *Financial Statements.*

(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†	Israeli Stock Option Plan, dated 2001, as amended as of July 7, 2003 (previously filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
10.2†	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).
10.3†	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).
10.4†	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).
10.5†	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).
10.6†	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).

10.7†	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).
10.8†	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).
10.9†	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).
10.10†	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).
10.11†	Executive Director Appointment Letter, dated as of June 1, 2007, for Dr. Andrew L. Pearlman (previously filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
10.12†	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).
10.13†	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).
10.14†	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).
10.15†	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).
10.16†	Strategic Advisory Board Agreement, dated as of December 10, 2010, between the Company and Isaac Blech (previously filed as Exhibit 10.31 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).
10.17†	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).
10.18†	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).

10.19†	Resignation Agreement dated as of November 9, 2011 between Dr. Baruch Stern and Medgenics Medical Israel Ltd. (previously filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011 (File No. 001-35112) and incorporated herein by reference).
10.20	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).
10.21	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).
10.22	Exchange of Scientific Materials and Data Agreement, dated as of January 25, 2010, between the Company and Baylor College of Medicine (previously filed as Exhibit 10.51 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).
10.23	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).
10.24	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).
10.25	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).
10.26	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).
10.27	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).
10.28	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).
10.29	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).

10.30	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).
10.31	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).
10.32	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).
10.33	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).
10.34	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).
10.35	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).
10.36	Broker Agreement, dated as of November 28, 2007, between Medgenics, Inc. and SVS Securities PLC (previously filed as Exhibit 10.43 to the Company's Registration Statement on Form S-1 filed November 5, 2010 (File No. 333-170425) and incorporated herein by reference).
10.37	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).
10.38	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: March 14, 2013

By: /s/ Andrew L. Pearlman
Andrew L. Pearlman
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.

Name	Title	Date
/s/ Andrew L. Pearlman Andrew L. Pearlman	President, Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2013
/s/ Phyllis K. Bellin Phyllis K. Bellin	Vice President – Administration, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 14, 2013
/s/ Sol J. Barer Sol J. Barer	Chairman of the Board of Directors	March 14, 2013
/s/ Eugene A. Bauer Eugene A. Bauer	Director	March 14, 2013
/s/ Joel S. Kanter Joel S. Kanter	Director	March 14, 2013
/s/ Stephen D. McMurray Stephen D. McMurray	Director	March 14, 2013
/s/ Alastair Clemow Alastair Clemow	Director	March 14, 2013
/s/ Isaac Blech Isaac Blech	Director	March 14, 2013

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