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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K



09010607

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

For the fiscal year ended December 31, 2008

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

For the transition period from to

COMMISSION FILE NUMBER 000-52691

MODIGENE INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada

(State or other jurisdiction of incorporation or organization)

20-0854033

(IRS Employer Identification No.)

3 Sapir Street, Weizmann Science Park
Nes-Ziona, Israel 74140

(Address of principal executive offices) (zip code)

Registrant's Telephone Number, Including Area Code: (866) 644-7811

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

Title of each class

Name of Each Exchange On Which Registered

None

N/A

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

Common Stock, par value \$0.00001 per share

(Title of Class)

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

Yes

No

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Section

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Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange 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 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

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 if the Act).

Yes No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: \$22,286,297.78, based on the last price at which the shares were sold on June 30, 2008 of \$0.87 per share.

As of March 10, 2009, the registrant had 35,549,028 shares of Common Stock, par value \$0.00001 per share, issued and outstanding.

Documents Incorporated by Reference: Portions of the Proxy Statement for the registrant's 2009 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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SIGNATURES

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“SAFE HARBOR” STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This document contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. You can identify such forward-looking statements by the words “expects,” “intends,” “plans,” “projects,” “believes,” “estimates,” “likely,” “goal,” “assumes,” “targets” and similar expressions and/or the use of future tense or conditional constructions (such as “will,” “may,” “could,” “should” and the like). In the normal course of business, Modigene Inc. (“Modigene” or the “Company”), in an effort to help keep its stockholders and the public informed about the Company may, from time to time, issue such forward-looking statements, either orally or in writing. Generally, these statements relate to business plans strategies or opportunities, and/or projected or anticipated benefits or other consequences of such plans, strategies, or opportunities, including anticipated revenues or earnings. Modigene bases the forward-looking statements on its current expectations, estimates and projections. Modigene cautions you that these statements are not guarantees of future performance and involve risks, uncertainties and assumptions that Modigene cannot predict. In addition, Modigene has based many of these forward-looking statements on assumptions about future events that may prove to be inaccurate. Therefore, the actual results of future events described in such forward-looking statements in this Annual Report, or elsewhere, could differ materially from those stated in such forward-looking statements. Among the factors that could cause actual results to differ materially are the risks and uncertainties discussed in this Annual Report, including, without limitation, the risk factors described under Item 1A of this Annual Report.

References in this Report on Form 10-K to “Modigene,” “the Company,” “we,” “us” and “our” refer to Modigene Inc., a Nevada corporation, and its wholly-owned subsidiaries taken as a whole, unless otherwise stated or the context clearly indicates otherwise.

Disclosures set forth in this Annual Report on Form 10-K are qualified by the section captioned “Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995” and other cautionary statements set forth elsewhere in this Annual Report.

PART I

Item 1. Business

History

We were originally formed under the name LDG, Inc. in August 2003 as the parent company of Liaison Design Group, LLC. On May 11, 2000, Sandra Conklin and Sambrick Communication formed Liaison Design Group, LLC as a North Carolina limited liability company to join their respective graphics design and marketing/advertising businesses. On March 10, 2003, Seamus Duerr was admitted as a member of Liaison Design Group. On September 26, 2003, the membership interests of Liaison Design Group were transferred to us in exchange for shares of our common stock.

On May 9, 2007, we entered into an Agreement and Plan of Merger and Reorganization with Modigene Acquisition Corp., our wholly-owned subsidiary, and Modigene Inc., a Delaware corporation, which we refer to in this Form 10-K as Modigene Delaware. Modigene Delaware is the parent company of ModigeneTech Ltd., an Israeli corporation. On May 9, 2007, pursuant to the merger agreement, Modigene Acquisition Corp. merged with and into Modigene Delaware, with Modigene Delaware remaining as the surviving corporation. As a result of the merger, Modigene Delaware and ModigeneTech became our wholly-owned subsidiaries and we acquired their existing business operations and changed our name to Modigene Inc. At the closing of the merger, the former stockholders of Modigene Delaware received shares of our common stock in exchange for their shares of Modigene Delaware. As a result, at the closing of the merger we issued an aggregate of 13,588,552 shares of our common stock to the former stockholders of Modigene Delaware. In addition, we assumed the obligations under outstanding options and warrants previously issued by Modigene Delaware.

Prior to the closing of the merger with Modigene Delaware, we transferred all of our former operating assets and liabilities to our wholly-owned subsidiary Liaison Design Group, and simultaneously with the closing of the merger we sold all of the outstanding membership interests of Liaison Design Group to Sandra Conklin, Seamus Deurr and Sambrick Communications, Inc. In connection with the sale of membership interests, 34,920,633 shares of our common stock that were held by the purchasers prior to the merger were surrendered and cancelled without further consideration. As a result, our stockholders immediately prior to the merger held 7,333,339 shares of our common stock, which were retained in the merger.

Concurrently with and in contemplation of the merger, we completed a private placement of our securities, 6,418,814 units of which were sold on May 9, 2007, and an additional 2,247,858 units of which were sold on May 21, 2007, for a total of 8,666,672 units sold in the private placement. Each unit sold in the offering consisted of one share of our common stock and a warrant to purchase one-quarter (25%) of a share of our common stock. Also simultaneously with the closing of the merger, we sold an additional 5,377,660 shares of our common stock, plus warrants to purchase 333,333 shares of our common stock, to four strategic investors led by Dr. Phillip Frost and Dr. Jane Hsiao, who were appointed as directors upon the closing of the transactions described in this section, for total consideration of \$2,000,000. On May 21, 2007, we issued an additional 155,673 shares of our common stock for no additional consideration to these investors, for a total of 5,533,333 shares issued to this investor group.

As a result of these transactions, the former stockholders of Modigene Delaware acquired approximately 38.7% of our then-outstanding shares of common stock, new investors were issued approximately 40.4% of our then-outstanding common stock, and our former stockholders retained approximately 20.9% of our then-outstanding common stock. The business of Modigene Delaware and ModigeneTech became our business on a going-forward basis. Accordingly, the description of our business included in this Form 10-K is a discussion of the business of Modigene Delaware and ModigeneTech to the extent that it relates to periods prior to our acquisition of them on May 9, 2007.

Overview

We are a development stage biopharmaceutical company utilizing patented technology to develop longer-acting, proprietary versions of already approved therapeutic proteins that currently generate billions of dollars in annual global sales. We have obtained certain exclusive worldwide rights from Washington University in St. Louis, Missouri to use a short, naturally-occurring amino acid sequence (peptide) that has the effect of slowing the removal from the body of the therapeutic protein to which it is attached. This Carboxyl Terminal Peptide (CTP) can be readily attached to a wide array of existing therapeutic proteins, stabilizing the therapeutic protein in the bloodstream and extending its life span without additional toxicity or loss of desired biological activity. We are using the CTP technology to develop new, proprietary versions of certain existing therapeutic proteins that have longer life spans, giving our products greatly improved therapeutic profiles and distinct market advantages.

We believe our products in development will provide several key advantages: dramatic reduction in the number of injections required to achieve the same or superior therapeutic effect from the same dosage; extended patent protection as proprietary new formulations of existing therapies; faster commercialization with greater chance of success and lower costs than those typically associated with a new therapeutic protein; and manufacturing using industry standard biotechnology based protein production processes.

The first novel protein containing CTP technology has been recently submitted for approval to the European Medicines Agency (EMA) after successful completion of a Phase III clinical study conducted by the Dutch multinational biotechnology company Organon International Inc., now part of Schering-Plough Corp., which licensed the technology directly from Washington University (prior to the formation of Modigene Delaware) only for application to Follicle Stimulating Hormone (FSH) and three other hormones, human Chorionic Gonadotropin (hCG), Luteinizing Hormone (LH) and Thyroid-Stimulating Hormone (TSH).

Worldwide sales of therapeutic proteins were approximately \$87 billion in 2008 and are expected to steadily increase in the coming years.¹ Our internal product development program is currently focused on extending the life span of the following biopharmaceuticals, which together address an established market in excess of \$15 billion:

- Human Growth Hormone (hGH)
- Interferon β
- Glucagon-Like Peptide-1 (GLP-1)
- Erythropoietin (EPO)

Worldwide sales of hGH are estimated at \$2.7 billion, those of EPO are estimated at \$11.8 billion, those of interferon β are estimated at \$5.0 billion, and GLP-1 analogues have recently reached the market, and are expected to grow

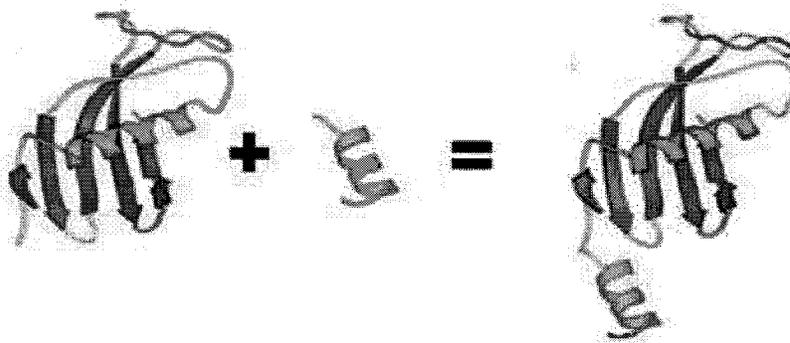
¹ Ernst & Young, Beyond Borders Global Biotech Report (2008).

significantly.² We believe that the CTP technology will be broadly applicable to these as well as many other of the best-selling therapeutic proteins in the market and will be attractive to potential partners because it will allow them to extend proprietary rights for therapeutic proteins with near-term patent expirations.

Discovery, Development and Clinical Experience with CTP Technology

Our core technology was developed by Washington University in St. Louis, while investigating the female hormone hCG, which facilitates pregnancy by maintaining production of progesterone and stimulating development of the fetus.

hCG has a long life span of up to 2 days, meaning that the body is slow to break it down. LH is another female hormone having a chemical composition (amino acid sequence) very close to that of hCG. LH has a very short life span of 20 minutes. Scientists at Washington University discovered that the only difference between hCG and LH is a short amino-acid sequence present in hCG and not in LH which they called “CTP,” for Carboxyl-Terminal Peptide. This is shown schematically below. When produced in mammalian cells, this CTP is heavily modified by sugars being added (a process called glycosylation). Through numerous experiments, it was confirmed that CTP was responsible for the longer life span of hCG as compared to LH. Washington University then performed additional experimentation adding CTP to different therapeutic proteins and the results showed that the CTP-modified proteins had dramatically increased life span.



Modigene’s core technology is the use of a short, naturally occurring amino acid sequence (CTP) to slow the removal of therapeutic proteins from the body without increasing toxicity or altering the overall biological activity

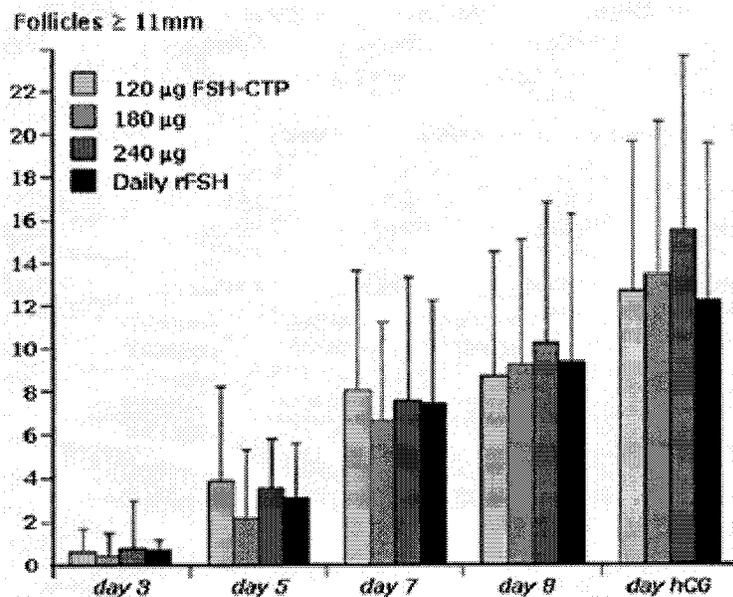
Our scientific founder, Dr. Fuad Fares, was a post-doctoral student at Washington University and worked on these findings and experiments. When Dr. Fares returned to Israel in 2001, he formed ModigeneTech to license the CTP technology from Washington University for certain therapeutic indications.

Prior to Dr. Fares’ completion of our initial license agreement with Washington University, the Dutch biotech company Organon, now part of Schering-Plough Corp., licensed the CTP solution to be used in conjunction with four endocrine proteins: FSH, hCG, TSH and LH. Organon’s goal was to develop a longer-lasting version of their FSH product, marketed as Follistim and required to be injected on a daily basis. There have been several attempts to create a long-lasting version of FSH utilizing existing technologies that compete with our CTP technology, including a PEGylated version, all of which have been abandoned or terminated.

In July 2008, Schering-Plough announced successful top-line data from its Phase III ENGAGE trial demonstrating that women receiving a single injection of FSH-CTP achieved the same pregnancy rates as women receiving seven consecutive daily injections of FSH, a primary endpoint of the study. This 1,509 patient trial was the largest double-blind fertility trial ever conducted. In December 2008, Schering-Plough announced that the European Medicines Agency (EMA) has accepted for review its Marketing Authorization Application for FSH-CTP.³ We believe that Organon’s success to date, in conjunction with our own research and development efforts, indicates that the addition of CTP to existing therapeutic proteins is commercially valuable. We are now the exclusive licensee for the utilization of CTP technology in all therapeutic proteins, peptides and their modified forms except for human FSH, LH, TSH and hCG.

² Maggon K., Billion dollar biologic medicines of 2007.

³ Ernst & Young, Beyond Borders Global Biotech Report (2008).



Stimulation of egg follicle growth in women preparing for IVF. Standard treatment of daily injection of rFSH (rightmost bar in each day's group) is compared to a single injection of FSH-CTP in one of three dose levels. At the days shown, large (growing) follicles were detected by ultrasound. There were at least as many large follicles stimulated by each of the FSH-CTP doses as with the control group.⁴

Opportunity Background

Overview of Therapeutic Proteins

Therapeutic proteins are proteins that are either extracted from human cells or engineered and produced in the laboratory for pharmaceutical use. The majority of therapeutic proteins are recombinant human proteins manufactured using non-human cell lines that are engineered to contain certain human genetic sequences which cause them to produce the desired protein. Recombinant proteins are an important class of therapeutics used to replace deficiencies in critical blood borne growth factors and to strengthen the immune system to fight cancer and infectious disease. Therapeutic proteins are also used to relieve patients' suffering from many conditions, including various cancers (treated by monoclonal antibodies and interferons), heart attacks, strokes, cystic fibrosis and Gaucher's disease (treated by enzymes and blood factors), diabetes (treated by insulin), anemia (treated by erythropoietins), and hemophilia (treated by blood clotting factors).

The U.S. Food and Drug Administration (FDA) has approved 75 therapeutic proteins, also known as biopharmaceuticals, and there are more than 500 additional proteins under development. Worldwide sales of therapeutic proteins were reported to be approximately \$87 billion in 2008.⁵ To date, much of the growth has been in sales of erythropoietins (used to treat anemia) and insulins (used to treat diabetes). Many of the proteins currently on the market will lose the protection of certain patent claims over the next 15 years. In addition, many marketed proteins are facing increased competition from next-generation versions or from other therapeutic proteins approved for the same disease indications.

Because proteins are broken down in the gastrointestinal system, marketed therapeutic proteins must be administered by injection. Once in the bloodstream, therapeutic proteins are broken down by enzymes and cellular activity, as well as filtered out of the blood by the kidneys. Therefore, injections must be given frequently to achieve effective therapeutic levels. A large market opportunity exists for new versions of proven therapeutic proteins that remain active longer, thereby reducing the number of required injections and optimizing therapeutic results and patient acceptability. However, existing approaches to creating modified therapeutic proteins are generally based on the addition of synthetic, non-protein elements that result in problems such as loss of desired biological activity, toxicity of the modified protein and increased manufacturing complexity and cost. Despite these challenges, several longer-lasting modified therapeutic proteins currently on the market have been demonstrated to be successful. Each of these improved therapeutics was custom-designed with great effort.

⁴ P. Devroey et al., *The Journal of Clinical Endocrinology and Metabolism* 89: 2062-70 (2004).

⁵ Ernst & Young, *Beyond Borders Global Biotech Report* (2008).

Attempts to Extend the Life Span of Therapeutic Proteins

Several strategies have been devised in recent years to extend the life span of therapeutic proteins by slowing their clearance from the body. These strategies have included two main techniques:

- Increasing the size of the therapeutic protein. This is achieved either by attaching large polymeric chains to the protein (PEGylation) or by attaching other large, non-active proteins that have longer life spans compared to the target therapeutic protein.
- Altering the physical structure of the therapeutic protein. This is achieved by adding carbohydrate structures to the therapeutic protein (glycosylation) through modifications of the original genetic sequence of the protein. These additional “sugar chains” slow the clearance of the therapeutic protein from the bloodstream.

Limitations of Existing Life Span Extension Solutions

There are several fundamental issues with the existing technologies that attempt to create longer-lasting versions of therapeutic proteins. If the size of the protein is increased by way of attaching large polymeric chains or another protein, the end result is a very large protein. Because most therapeutic proteins work by binding to specific receptors, the new “bulkiness” may prevent them from achieving the desired result. The smaller the protein, the more significant the effect of the size increase may be. The successful attempts at increasing the size of therapeutic proteins, while preserving substantial activity, have been relatively few, and have been with proteins that are already large. Even so, the biological activity of the modified protein has been significantly less than that of the unmodified protein, and thus requires a higher injected dose as compared to the unmodified protein’s usual dosage. One typical method to achieve the desired size increase is to add long polymers of polyethylene glycol (PEG) to a protein; however, such method has in the past resulted in the creation of foreign structures to which the immune system may adversely react. When this happens, the immune system also works to remove the modified protein from the bloodstream, defeating the purpose of the original modification. It can also lead to additional negative effects, such as reaction at the injection site.

Another technique, glycosylation, requires custom alterations (point mutations) to the protein’s genetic structure to increase its life span. The resulting modified protein is entirely new and often generates unexpected adverse reactions, resulting in potentially toxic effects. To date, creating a protein with a longer life span that is not toxic has been a lengthy trial and error process.

Although the existing modification technologies have been tried on almost all therapeutic proteins, only three modified proteins have been commercially successful: two developed by Amgen Inc., and one independently developed by Schering-Plough Corporation and Roche Pharmaceuticals. Each of these marketed longer-lasting therapeutic proteins has captured multi-billion dollar annual sales and is a leader in its respective market based upon annual sales:

- Utilizing PEGylation, Schering-Plough and Roche independently developed PEG-INTRON and PEGASYS, therapeutic proteins with a longer life span than that of regular Alpha interferon (used for treating Hepatitis B and C), and which generated sales in 2007 of \$2.55 billion.
- Utilizing PEGylation, Amgen developed Neulasta, an anti-neutropenia therapeutic protein with a longer life span than that of regular G-CSF, and which generated sales in 2007 of \$2.7 billion.⁶
- Utilizing additional glycosylation, Amgen developed Aranesp, an anti-anemia therapeutic protein with a longer life span than that of regular EPO, and which generated sales in 2007 of \$4.2 billion.

These products, collectively having revenues of more than \$9 billion a year, clearly indicate the potential value of developing improved therapeutic proteins.

Our Solution

Through our license agreement with Washington University, we have secured exclusive, worldwide rights to use the CTP technology with respect to all natural and non-natural therapeutic proteins and peptides (other than LH, TSH, FSH and

⁶ Maggon K., Billion dollar biologic medicines of 2007.

hCG), including hGH, EPO, interferon β and GLP-1. Our solution to creating proprietary, enhanced longevity protein therapeutics is CTP, a short, naturally-occurring amino acid sequence that has the effect of slowing the removal and/or breakdown of the therapeutic protein to which it is attached. Using standard recombinant DNA techniques, the CTP cassette can be readily attached in one or more copies to a wide array of existing therapeutic proteins. When these proteins are produced in mammalian cells, the CTP portion undergoes a natural process in which special carbohydrate chains are attached (O-linked glycosylation). This additional CTP piece, along with its carbohydrate chains, stabilizes the therapeutic protein in the bloodstream and greatly extends its life span, without additional toxicity or loss of its desired biological activity. This is quite distinct from other methods used to extend protein life span, which require the addition to the therapeutic drug of large proteins or of synthetic, non-protein elements that may result in problems such as loss of desired biological activity or toxicity of the modified protein, as well as increased manufacturing complexity and cost. Moreover, CTP-modified proteins can be manufactured using established and widely used mammalian protein expression systems (cell lines). Therefore, the technology risks are minimized, while the benefits of the CTP technology can be substantial.

There are two existing biopharmaceuticals that utilize CTP technology. The first product is hCG, of which CTP is naturally a part. Besides being present normally in high amounts during pregnancy, it is also given therapeutically to women or men as a fertility treatment (sold by Serono, Organon and Ferring). The second product is FSH-CTP, in clinical development by Organon as described above. The data from the use in humans of these two products gives us confidence that the CTP technology may be able to address the major problems faced by the other attempted approaches to increase protein lifespan. Data from these products reassures us that CTP can be used safely in humans and that it is effective in extending the serum lifetime and activity in humans.

We believe the clinical development program for our drugs will be faster, less expensive and more predictable than those conducted for existing therapeutic proteins. We can base the design of our studies, the inclusion criteria, clinical endpoints and sample sizes, on the knowledge gained from development of the predecessor drugs, with the assurance that these have been accepted by regulatory authorities in the past. In addition there are usually surrogate markers for clinical efficacy that have been defined and accepted by the medical community. These can provide easier and faster ways of learning at an early stage the correct dosing range and frequency. In some cases, they can even be used as definitive clinical trial endpoints. These factors drive down the time and costs associated with clinical trials.

Research & Development: Our Development Programs

We are currently pursuing the development and commercialization of four products – Human Growth Hormone, Interferon β , Glucagon-Like Peptide-1 and Erythropoietin – which collectively address an established market in excess of \$15 billion. The aggregate cost of our research and development programs during the 2008 fiscal year was \$5,527,102 and during the 2007 fiscal year was \$2,667,733.

Human Growth Hormone (hGH)

Market Opportunity

Growth hormone deficiency (GHD) is a pituitary disorder resulting in short stature in children and other physical ailments in both children and adults. GHD occurs when the production of growth hormone, secreted by the pituitary gland, is disrupted. Since growth hormone plays a critical role in stimulating body growth and development, and is involved in the production of muscle protein and in the breakdown of fats, a decrease in the hormone affects numerous body processes.

Recombinant hGH is used for the long-term treatment of children and adults with growth failure due to inadequate secretion of endogenous growth hormone. The primary indications it treats in children are growth hormone deficiency, kidney disease, Prader-Willi Syndrome and Turner's Syndrome. In adults, the primary indications are replacement of endogenous growth hormone and the treatment of AIDS-induced weight loss. The annual market for hGH was \$2.7 billion in 2007, with six companies then marketing versions of the therapeutic protein.

In addition to its current use, hGH has been proven to promote a number of lifestyle benefits including weight loss, increased energy levels, enhanced sexual performance, improved cholesterol, younger, tighter, thicker skin, and reduced wrinkles and cellulite. We expect the hGH market to expand significantly as hGH moves beyond therapeutic treatment to include the treatment of lifestyle issues.

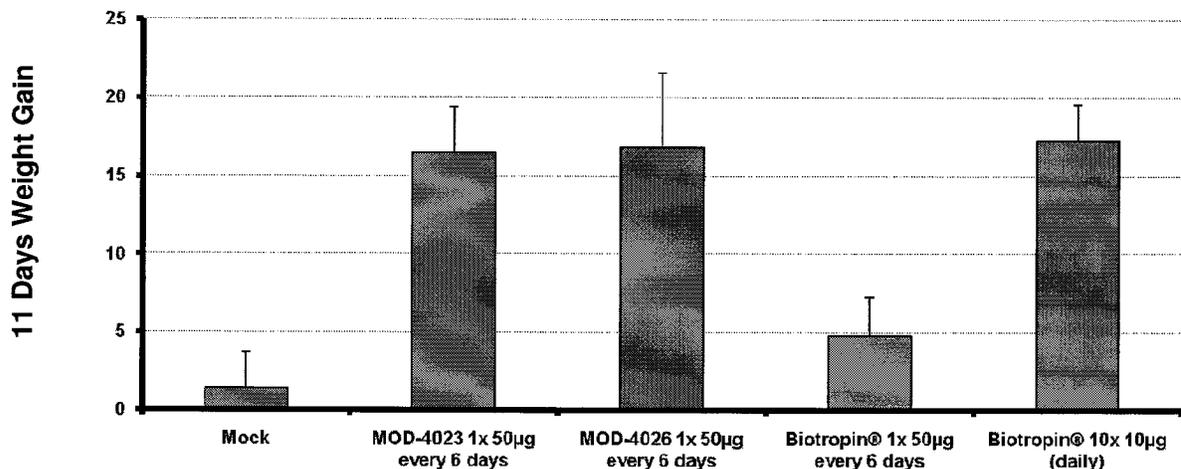
Current Products

Prior to the advent of recombinant versions, growth hormone was purified from human cadavers. For the past 20 years, recombinantly produced protein has been supplied to the market by an increasing number of companies. Current products on the U.S. market are Nutropin (Genentech), Genotropin (Pfizer), Humatrope (Eli Lilly), Norditropin (Novo Nordisk), Serostim (Merck-Serono) and Omnitrope (Novartis).

Modigene's hGH-CTP Program

Patients using hGH receive daily injections six or seven times a week. This is particularly burdensome for pediatric patients. We believe a significant market opportunity exists for a longer-lasting version of hGH that would require fewer injections.

We have successfully cloned and expressed several variants of hGH-CTP. The in-vivo biological activity of the hGH-CTP variants has been tested using the standard hGH animal model, named the "Weight Gain Assay." In that animal model we conducted a comparative study of the effect of daily injection of commercial hGH, versus single weekly injection of hGH-CTP, on the growth of hypophysectomized rats – rats that had their pituitary gland removed by surgery. The rats cannot continue to grow and add weight without their pituitary gland, unless they get supplemental hGH via injection. During a period of 11 days, we injected one group of rats with 11 consecutive daily injections of commercial hGH, while other groups have been injected once every six days with our long-lasting hGH-CTP. As shown below, the results demonstrate that a single injection per week of our hGH-CTP is highly effective in inducing growth, and as effective as six daily injections of commercial hGH. We intend to initiate the first human clinical trial of CTP-modified hGH during 2009. Given the enormous clinical experience with growth hormone over many decades, accepted surrogate markers of its activity in the body and clear clinical trial endpoints, we expect our clinical program to progress rapidly, predictably, and at relatively low cost. In November 2007, we received approval from the Office of the Chief Scientist of the Israeli government (OCS) for a grant supporting the product and clinical development of our hGH-CTP product. The grant will provide cash reimbursements of 30% to 50% of our development expenses for the hGH-CTP product. The project budget is estimated at \$10 million over four years (2008 through 2011). In January 2009, following the announcement of promising results from our pilot hGH-CTP toxicity study in primates, we received approval for a second-year special grant from the OCS in support of our hGH-CTP development program. The grant will provide cash reimbursements of 40% of cash expenses paid for hGH-CTP product development during the period between September 2008 and August 2009, up to a limit of 10 million NIS (approximately \$2.6 million).



11 days of incremental weight gain was measured in hypophysectomized male rats following two injections – once every 6 days SC injection of 50 µg/rat. The control group was a standard protocol of once daily injection of 10 µg/rat of commercial rhGH Biotropin. The experiment was conducted according to USP official monograph: Somatotropin.

Pharmacokinetic animal models show that the durability of the hGH-CTP, as measured by its $T^{1/2}$, is approximately 6.8x longer than commercial hGH when injected subcutaneously. In addition, the serum availability of hGH-CTP is approximately 10.6x better than commercial hGH for subcutaneous administrations.

In January 2009, we reported results from a pilot toxicity study in primates designed to assess the safety of hGH-CTP, as well as to provide preliminary information on the approximate injection frequency that will be needed in human patients. The study was designed to elicit potential adverse effects from a single, very large dose of hGH-CTP. The pilot study included a group of primates that received a single injection of hGH-CTP containing a dose that was 1,040 times the daily dose of growth hormone recommended for use in human patients. No adverse effects were observed in any of the primates. In addition, the half-life and AUC (area under the curve) of hGH-CTP as measured in primates support a potential once-weekly or bi-monthly injection frequency in humans.

Erythropoietin (“EPO”)

Market Opportunity

The level of red blood cells in the body at any given time depends on a protein hormone called Erythropoietin (EPO). The kidneys make EPO and it travels to the bone marrow, where it stimulates the production of red blood cells. Individuals with chronic kidney failure, chemotherapy patients and HIV/AIDS patients on AZT therapy suffer from low levels of EPO. Without sufficient EPO, the level of red blood cells drops, which causes anemia. Symptoms of anemia can be vague, but most commonly, people with anemia report a feeling of weakness or fatigue. More severe anemia leads to shortness of breath, and can lead to heart failure in the elderly.

In addition to its major use in patients with chronic kidney failure and on chemotherapy, EPO is also used in patients who may require a blood transfusion or undergo surgery where blood loss is expected. In these cases, EPO is given in advance as a precaution. The bone marrow produces more red blood cells, and if blood is lost during the operation, there is still enough to sustain the patient.

Annual sales of EPO were estimated to be \$11.8 billion in 2007.⁷ Of this, Amgen’s long-acting EPO, Aranesp, currently sells \$4.2 billion per year.

Current Products

Recombinant EPO was launched as a pharmaceutical product by Amgen for treatment of anemia resulting from chronic renal failure in 1989 under the brand name Epogen. In 1991 it was also approved for treating anemia resulting from cancer chemotherapy. Johnson & Johnson (J&J) markets EPO under license from Amgen for cancer chemotherapy under the brand names Procrit (US) and Eprex (ex-US). A longer-acting erythropoietin analogue, darbepoetin (dEPO), also known as novel erythropoiesis-stimulating protein (NESP), was launched by Amgen under the brand name Aranesp in 2001.

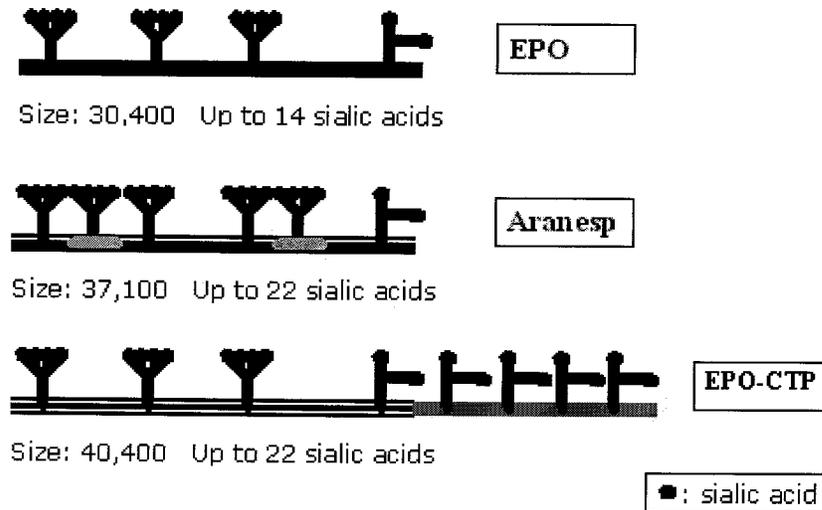
Amgen’s patents have so far prevented other companies from entering the U.S. market. Even though the patents are all based on work done in the early 1980s, the last of them will not expire until 2015, thirty-two years after the date of the original application. Outside the United States, Amgen’s patents did not prevail and EPO is also available from Roche and Chugai under the brand names NeoRecormon and Epogin. Also in Europe, EPO produced by different technology will soon be available from Shire as Dynepo (originally developed by Transkaryotic). Unlike existing forms of pharmaceutical EPO manufactured in cultured animal cells, Dynepo is made in cultured human cells. It is therefore expected to have an authentic human form of glycosylation. This characteristic may make it a longer-acting product than existing brands, but clinical data have not yet been made public. A long-acting PEGylated form is in development by Roche as CERA.

EPO is generally injected subcutaneously (under the skin) by the patient, although it may also be given intravenously (through a vein). Several injections weekly are required for the original forms, but the long-acting forms may require injections only once every two weeks.

⁷ Maggon K., Billion dollar biologic medicines of 2007.

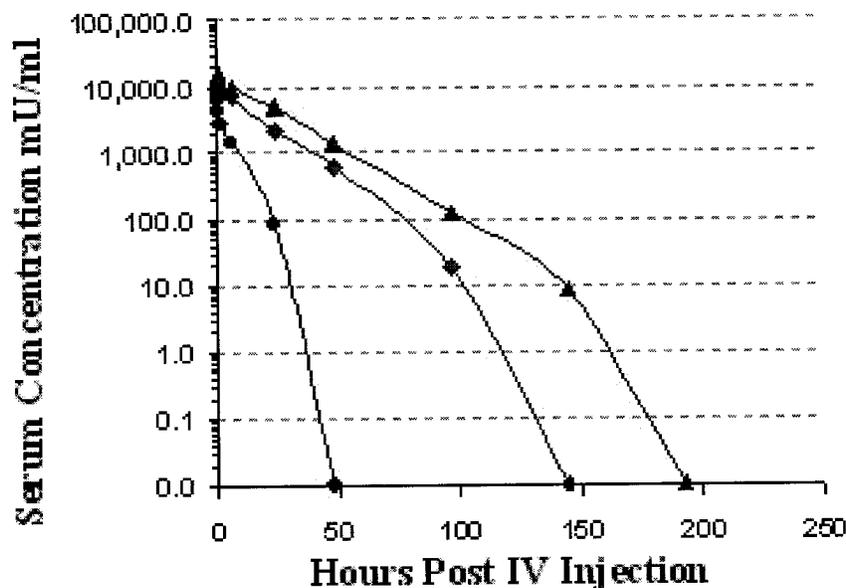
Modigene's EPO-CTP Program

Our scientists have created constructs of EPO with CTP attached, and demonstrated in rodents that EPO-CTP has extended serum lifetime and enhanced activity compared to equivalent amounts of EPO, and is at least as effective as Aranesp, Amgen's long-acting EPO. Aranesp was constructed as one of a very large number of mutants of EPO, each of which was laboriously cloned, expressed and tested for activity. By comparison, only a single cloning experiment was required to engineer each variant of EPO-CTP. Schematic structures of EPO, Aranesp and EPO-CTP with a single CTP cassette are shown below (not to scale). It can be seen that EPO-CTP with a single CTP cassette contains the same maximal number of sialic acids as the terminal residues on its carbohydrate chains as does Aranesp. These sialic acids have been described by Amgen to be a major factor in determining serum half-life. A secondary contributor is molecular weight, and EPO-CTP appears to benefit from this factor, especially in EPO-CTP variants with three CTP cassettes.



Schematic comparison of EPO with its long-acting modified versions. Amgen's Aranesp has two mutations which create new sites for glycosylation. EPO-CTP adds a naturally occurring peptide that is automatically glycosylated. The EPO-CTP has the same number of chains ending in the sugar sialic acid, which is a major contributor to long serum half-life.

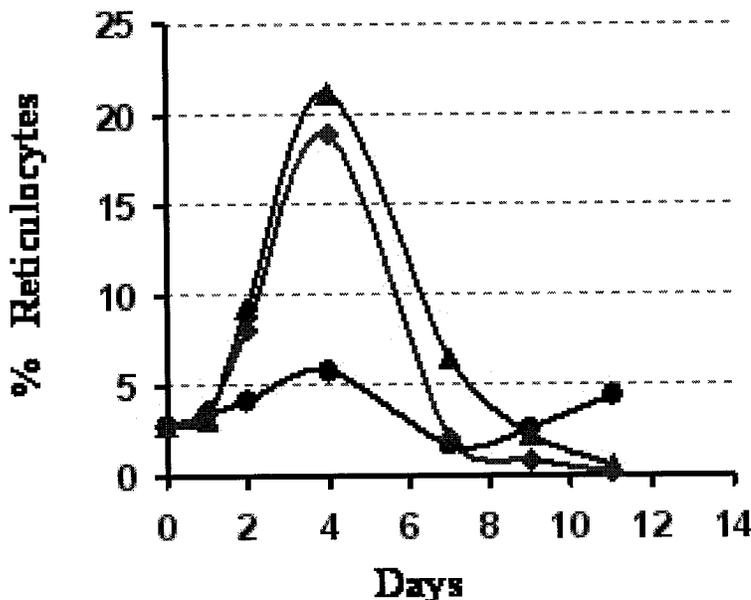
The in-vivo biological activity of the EPO-CTP variants has been tested using the standard EPO animal model. In that animal model we conducted a comparative study of the biological effect of single injection of commercial EPO, single injection of Aranesp, and a single weekly injection of EPO-CTP, on mice. The hemoglobin levels, as well as other parameters, of the mice were measured. In addition, the half-life (durability) of EPO, Aranesp, and EPO-CTP was measured. As shown below, the results demonstrate that (i) a EPO-CTP has a half-life higher by 33% than that of Aranesp, (ii) a single injection per week of our EPO-CTP is highly effective in inducing immature red blood cells, as well as hemoglobin levels, and (iii) a single injection per week of our EPO-CTP has a stronger biological effect than that of a single injection per week of Aranesp.



Single Injection of 15µg/kg

- ▲ EPO-3-CTPs
- Aranesp [Amgen]
- EPO

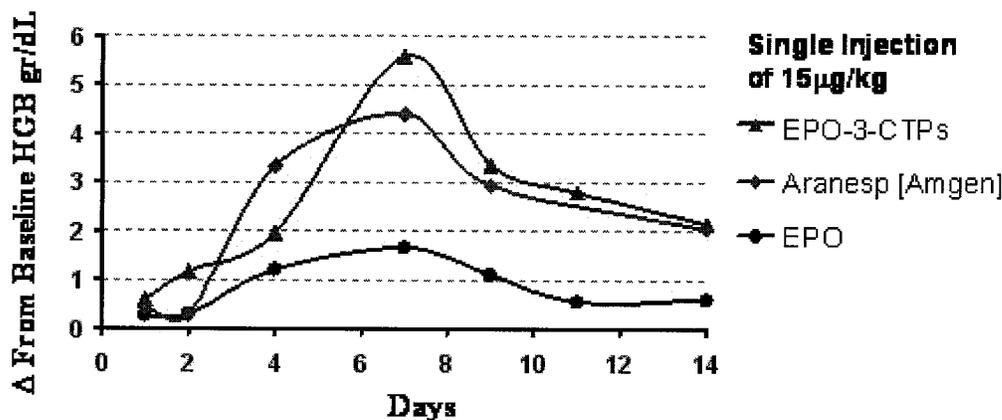
EPO with 3 CTP units (upper curve) has a longer half-life than that of both Aranesp and EPO – and therefore it remains in the blood for longer periods.



Single Injection of 15µg/kg

- ▲ EPO-3-CTPs
- Aranesp [Amgen]
- EPO

Single injection of EPO with 3 CTP units (upper curve) is highly effective at stimulating immature red blood cells in the red bone marrow, and better than a single injection of Aranesp or EPO.



Single injection of EPO with 3 GTP units (blue curve) is highly effective at stimulating hemoglobin formation, and better than a single injection of Aranesp or EPO. The chart displays the increase in hemoglobin levels.

Interferon β

Market Opportunity

Beta interferon is a drug used to reduce the frequency and severity of relapses afflicting people suffering from multiple sclerosis (MS). MS is an autoimmune neurological disorder affecting the insulating myelin layers of the brain and spinal cord. If unchecked, over time the immune system attack on the myelin leads to poor coordination, severe disabilities and premature death.

Annual sales of beta interferon were estimated to be \$5.08 billion in 2007, selling under the product names Rebif by Merck-Serono, Inc., Betaseron/Betaferon by Schering AG and Avonex by Biogen Idec.⁸

Current Products for MS

Beta interferon is available as two different proteins with similar activity. Interferon β -1b (Betaseron) is a genetically altered protein produced in *E. coli* bacteria, and was the first product introduced for MS in 1993. Interferon β -1a is the natural sequence protein, produced in mammalian cells, and is glycosylated. It was introduced to the U.S. market in 1996 by Biogen Idec (Avonex), followed in 2002 by Serono's product Rebif, which is co-marketed by Pfizer. Betaseron is injected every other day subcutaneously, Avonex is given once per week by intramuscular injection and Rebif is given subcutaneously three times per week. Interferons have been shown to reduce the rate of MS relapses by 30-40%, and to slow the progression of disability in MS patients. None of the products on the market is a cure, but patients today who start early on interferon can suppress the disease enough that they are much less likely today to end up in a wheelchair than they were before these treatments were available.

In addition to the beta interferons sold by Biogen Idec, Schering and Serono, the other major product used for MS is Copaxone, developed by Teva and marketed together with Sanofi Aventis. Worldwide sales of Copaxone were \$1,713 million in 2007.⁹ Other drugs approved for MS include the chemotherapeutic Novantrone (Serono) and the biologic Tysabri (Biogen Idec), which is reserved for unresponsive cases due to potentially fatal adverse effects.

Modigene's Interferon β -1a-CTP Program

Modigene's IFN- β -CTP is produced in Chinese hamster ovary cells—the same cell line also used by Avonex[®] and Rebif[®]. We produced the protein and conducted in vitro and preclinical animal models of IFN- β -CTP. A single injection of IFN- β -CTP has shown the potential to require injection protocol of only once every two weeks, compared with two to four times for the current protocols with commercial IFN- β (Avonex[®] and Rebif[®]).

⁸ Maggon K., Billion dollar biologic medicines of 2007.

⁹ Teva press release, February 12, 2008.

Pharmacokinetic animal models show that the durability of the IFN- β -CTP, as measured by its $T^{1/2}$, is approximately 8.2x longer than commercial IFN- β when injected intravenously. In addition, the serum availability of IFN- β -CTP is approximately 24x better than commercial IFN- β , for intravenous administration.

The receptor specificity of IFN- β -CTP is identical to the commercial IFN- β , providing further indication that the increased longevity of IFN- β -CTP will not deteriorate any biological effect. In August 2008, we received approval from the OCS for a grant supporting the first year product and clinical development of our long-acting interferon- β drug, with cash reimbursements of 40% of our development expenses. The project budget is estimated at \$25 million over four years.

Glucagon-Like Peptide-1 (“GLP-1”)

Market Opportunity

Diabetes is a chronic disease in which a person's blood glucose levels are too high due to either a lack of insulin or the body's inability to use the insulin effectively. Insulin is an essential hormone that enables the absorption of glucose into the body's cells, which then use it as fuel. High glucose levels can damage blood vessels and lead to complications such as diabetic blindness, kidney diseases, heart diseases, strokes, peripheral neuropathy and vascular disease, leading to the amputation of limbs. The risks of these complications can be reduced significantly with close control of blood glucose. Despite this, two thirds of deaths in diabetes patients are attributed to cardiovascular disease.

Type 2 diabetes, usually diagnosed in adults (although increasingly in obese children and adolescents), occurs when the body does not produce sufficient insulin or the insulin produced is not being utilized effectively (a condition called insulin resistance). There are a number of oral drugs available for the treatment of this type of diabetes, although insulin injections may need to be taken when the oral drugs are unable to control blood glucose levels. Between 90% and 95% of all diabetics have Type 2 diabetes.

Diabetes is the most common endocrine disorder in the United States and is the fifth leading cause of death in the country (excluding accidents). The prevalence of Type 2 diabetes has tripled in the last 30 years, due in large part to the increase in obesity. Type 2 diabetes affects more than 17 million Americans, over 6% of the total population,¹⁰ and in 2002 was estimated to cost the country \$132 billion.¹¹ Worldwide, the World Health Organization currently estimates that as of the year 2000 diabetes affected some 177 million individuals, and projects that this number may increase to at least 300 million by 2025.¹² It is estimated that in 2002, worldwide spending on oral diabetes drugs and injected insulin for Type 2 diabetes was \$12.5 billion.¹³

Many patients' diabetes is poorly controlled despite use of oral drugs or insulin, and insulin therapy typically causes weight gain. Because obesity is a major factor in causing the diabetes, weight gain is highly undesirable. This has instigated a continued search for new and better anti-diabetic agents, leading to the discovery of GLP-1. GLP-1 is a peptide hormone that acts throughout the body to help maintain healthy blood sugar levels and to control appetite. In healthy individuals, GLP-1 levels rise during a meal to help the body utilize and control the elevation in blood sugar levels, but this response is blunted in Type 2 diabetics. GLP-1 also contributes to the health and survival of the insulin-producing cells in the body. GLP-1 analogues have recently reached the market, and sales are expected to grow rapidly.

There is also evidence that GLP-1 could be an important therapy for congestive heart failure,¹⁴ and it is being studied in clinical trials for that indication using continuous infusion.

Current Products

Type 2 diabetes is treated first with diet and exercise, then with oral pharmaceutical agents and finally with insulin. The U.S. market for oral diabetic drugs and insulin is significant. Despite the range of treatment options, a large fraction of patients do not manage to control their blood glucose levels adequately.

¹⁰ National Diabetes Information Clearinghouse (NIDDK/NIH).

¹¹ American Diabetes Association (ADA).

¹² World Health Organization (<http://www.who.int/mediacentre/factsheets/fs236/en/>).

¹³ From Business Communications Company, Inc. (BCC), a Connecticut, U.S., based business research firm specializing in biotechnology.

¹⁴ See review by H. Taegtmeyer, *Circulation* 110: 894-896 (2004).

The primary obstacle to the use of GLP-1 as a therapeutic for diabetes is its extremely short half-life of about five minutes in the body. For this reason, researchers have tried a number of approaches to overcome this problem. The first product to reach the market is a longer-lived GLP-1 analogue originally isolated from the gila monster, recently introduced to the market as Byetta (exenatide). Other attempts to address the short half-life have been to attach the peptide to a long-circulating protein, or to use continuous infusion, which for most patients is not practical.

Modigene's GLP-1-CTP Program

We believe it will be practical to apply our CTP technology across the board to greatly prolong the time therapeutic peptides circulate in the body. Our proof of concept for this approach will be to use it for GLP-1, which has proven therapeutic value. Construction of the recombinant DNA vectors and expression of GLP-1-CTP has begun.

Our Business Strategy

Our goal is to become a leader in the development and commercialization of longer-lasting, proprietary versions of already approved therapeutic proteins that currently generate billions of dollars in annual global sales, through the utilization of our CTP technology. Key elements of our strategy are to:

- ***Develop and commercialize improved versions of biopharmaceuticals that dramatically reduce the number of injections required to achieve the same therapeutic effect from the existing drugs.*** Based on the clinical track record of our CTP technology, as evidenced by the results of Schering-Plough's FSH-CTP Phase III clinical trial, we believe that the addition of CTP to therapeutic proteins significantly enhances the lifespan of those proteins, without any adverse effects. We expect these modified proteins to offer significant advantages, including less frequent dosing and possibly improved efficacy, over the original versions of the drugs now on the market, as well as to meet or exceed the pharmacokinetic profile of next-generation versions of the drugs now on the market.
- ***Leverage extensive existing clinical and regulatory experience with the original drugs to bring our improved versions of these biopharmaceuticals to market more quickly, at lower costs and with a clearer path to regulatory approval.*** Because there is a large knowledge base on the original products, the preclinical, clinical and regulatory requirements needed to obtain marketing approval are very well defined. In particular, clinical study designs, inclusion criteria and endpoints can be used that have already been accepted by regulatory authorities. There typically exist accepted surrogate markers for clinical efficacy, which can sometimes even be used as definitive trial endpoints, but at the least are highly informative of proper dose range and frequency. All of these factors drive down the time and costs associated with clinical trials, which represent up to 90% of product development costs for a typical therapeutic protein. In addition to lowering the costs and time to market, we believe the strategy of targeting drugs with proven safety and efficacy provides a better prospect of clinical success of our proprietary development portfolio as compared to *de novo* protein drug development. The possibility of delays due to regulatory safety concerns is also reduced as the FDA gains comfort with the safety profile of CTP-modified proteins (CTP is naturally present in the body, on the approved drug hCG and on FSH-CTP). We estimate that the average time to market and cost of clinical trials for our products could be up to 50% less than that required to develop a new therapeutic protein.
- ***Seek attractive partnership opportunities.*** We believe that the CTP technology is applicable to most therapeutic proteins and peptides that have been approved to date by the FDA, including many of the best-selling therapeutic proteins in the market. We believe that the proprietary rights provided by CTP technology, together with the clinical and compliance benefits, will be attractive to potential partners, either the originator of the therapeutic protein or their prospective competitors. We will seek to build a portfolio of commercially attractive partnerships in a blend of co-developments and licenses. Where possible, we will seek partnerships that allow us to participate significantly in the commercial success of each of the compounds.
- ***Leverage our core competencies.*** We believe that our CTP technology improves the drug properties of therapeutic proteins. We will continue to use our CTP technology to develop improved versions of protein drugs with proven safety and efficacy and to improve the therapeutic profiles of new drugs that will be developed by our partners. We will also continue to conduct exploratory drug development research in therapeutic peptides and Fab fragments of monoclonal antibodies, where our CTP technology, intellectual property and internal expertise provide us with opportunities.

Our Partnering Strategy

In addition to commercializing the three therapeutic proteins and one peptide discussed above, there are many additional product candidates we can pursue in an opportunistic fashion. We plan to pursue partnering deals with biotechnology companies that have a strategic interest in using our solution to develop longer-lasting versions of their existing therapeutic proteins or peptides, or those in development. We anticipate such partnerships will provide significant revenues in the form of license fees, milestone payments and royalties on sales, which will help to subsidize our research and development costs.

Intellectual Property

Through our wholly-owned subsidiary, ModigeneTech, we license intellectual property that is necessary to conduct our business from Washington University. We initially licensed core intellectual property pursuant to a non-exclusive license agreement entered into with Washington University in 2001 and amended such license in 2004 such that ModigeneTech became the exclusive licensee of the two key CTP patents in connection with 11 therapeutic proteins. Pursuant to the prior license agreement, Modigene Delaware issued a total of 221,979 shares of its common stock to Washington University (378,796 shares of our common stock on a post-merger basis). In February 2007 we entered into a new license agreement, which we refer to as the License Agreement, with Washington University that superseded the prior license agreement. Pursuant to the new License Agreement, Washington University granted Modigene the exclusive license to three CTP patents and expanded the field of use to all natural and non-natural therapeutic proteins and peptides (other than LH, FSH, TSH and hCG). Under the License Agreement, we have the right to sub-license the licensed patents. The License Agreement terminates in 2018 when the last of the patents licensed to us under the License Agreement expires, unless terminated earlier. Under the License Agreement, we were required to pay an initial fee of \$100,000 in installments over the 18 months following the effective date of the License Agreement. In addition, we are required to pay annual license maintenance fees of \$30,000 (payable until the first commercial sale); royalty fees of 1.5% to 5% from net revenues (with certain required minimum royalties after the first commercial sale of \$10,000, \$20,000 and \$40,000 for the first, second, and third year and beyond, respectively), and sub-licensing fees of 7.5% to 20% on sub-licensing payments. Pursuant to the License Agreement, we will also be responsible for milestone payments of \$15,000 for each molecule at investigational new drug application (IND) filing, \$30,000 at the initiation of a Phase II clinical trial and \$40,000 at the initiation of a Phase III clinical trial.

Pursuant to our License Agreement with Washington University, we have obtained an exclusive license to the key CTP patents that have been issued by the U.S. Patent and Trademark Office – U.S. #5,712,122, U.S. #5,759,818 and U.S. #6,225,449. We believe these patents provide broad and comprehensive coverage of the CTP technology, and we intend to aggressively enforce our intellectual property rights if necessary. In addition, unrelated to the patents from Washington University, we have filed, and will likely continue to file, patent applications covering specific CTP-modified molecules and CTP innovations, such as configurations, compositions and methods.

Competition

The pharmaceutical industry is highly competitive. We face significant competition from pharmaceutical companies and biotechnology companies that are researching and developing therapeutic proteins with enhanced life spans. Several pharmaceutical companies, such as Amgen, Eli Lilly and Company (through its acquisition of Applied Molecular Evolution), Nektar Therapeutics, ConjuChem Inc., Flamel Technologies S.A., Nautilus Biotech S.A. and Ambrx Inc. have marketed products or are involved with the development of therapeutic proteins with enhanced life spans.

These companies, as well as potential entrants into our market, have longer operating histories, larger customer or use bases, greater brand recognition and significantly greater financial, marketing and other resources than we do. Many of these current or potential competitors can devote substantially greater resources to the development and promotion of their products than we can.

Additionally, there has been consolidation within the pharmaceutical industry and larger, well-established and well-financed entities may continue to acquire, invest in or form joint ventures to gain access to additional technology or products. Any of these trends would increase the competition we face and could adversely affect our business and operating results.

Government Regulation

Regulation by governmental authorities in the United States and other countries will be a significant factor in the production and marketing of our products and our ongoing research and development activities. All of our products require rigorous preclinical and clinical testing and regulatory approval by governmental agencies prior to commercialization and are subject to pervasive and continuing regulation upon approval. The lengthy process of seeking approval and the subsequent compliance with applicable statutes and regulations, if approval is obtained, are very costly and require the expenditure of substantial resources.

In the United States, the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the safety and effectiveness standards for our products and the raw materials and components used in the production of, testing, manufacture, labeling, storage, record keeping, approval, advertising and promotion of our products on a product-by-product basis.

Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. After laboratory analysis and preclinical testing, we intend to file an IND with the FDA to begin human testing. Typically, this requires a three-phase human clinical testing program which itself is subject to numerous laws and regulatory requirements, including adequate monitoring, reporting, record keeping and informed consent. In Phase I, small clinical trials are conducted to determine the safety and proper dose ranges of our product candidates. In Phase II, clinical trials are conducted to assess safety and gain preliminary evidence of the efficacy of our product candidates. In Phase III, clinical trials are conducted to provide sufficient data for the statistically valid proof of safety and efficacy. The time and expense required for us to perform this clinical testing can vary and is substantial. We cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, the FDA, the Institutional Review Board monitoring the clinical trials or the IND sponsor may suspend the clinical trials at any time on various grounds, including a finding that subjects or patients are exposed to unacceptable health risk.

We cannot take any action to market any new drug or biologic product in the United States until our appropriate marketing application has been approved by the FDA. The FDA has substantial discretion over the approval process and may disagree with our interpretation of the data submitted. The process may be significantly extended by requests for additional information or clarification regarding information already provided. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians. Satisfaction of these and other regulatory requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our products on a timely basis, if at all. Success in preclinical or early stage clinical trials does not assure success in later-stage clinical trials. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses. Delays in obtaining, or failures to obtain regulatory approvals, would have a material adverse effect on our business.

Even after we obtain FDA approval, we may be required to conduct further clinical trials and provide additional data on safety and effectiveness. We are also required to gain separate clearance for the use of an approved product as a treatment for indications other than those initially approved. In addition, side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product's use and, potentially, withdrawal of the product from the market. Any adverse event, either before or after marketing approval, can result in product liability claims against us.

In addition to regulating and auditing human clinical trials, the FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of such products prior to providing approval to market a product. If after receiving FDA approval, we make a material change in manufacturing equipment, location or process, additional regulatory review may be required. We also must adhere to current Good Manufacturing Practice (GMP) regulations and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA also conducts regular, periodic visits to re-inspect our equipment, facilities, laboratories and processes following the initial approval. If, as a result of these inspections, the FDA determines that our equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations.

The requirements that we and our collaborators must satisfy to obtain regulatory approval by government agencies in other countries prior to commercialization of our products in such countries can be rigorous, costly and uncertain. In the European countries, Canada and Australia, regulatory requirements and approval processes are similar in principle to those in the United States. Additionally, depending on the type of drug for which approval is sought, there are currently two potential tracks for marketing approval in the European countries: mutual recognition and the centralized procedure. These review mechanisms may ultimately lead to approval in all European Union countries, but each method grants all participating countries some decision-making authority in product approval. Foreign governments also have stringent post-approval requirements including those relating to manufacture, labeling, reporting, record keeping and marketing. Failure to substantially comply with these on-going requirements could lead to government action against the product, the Company and/or its representatives.

The levels of revenues and profitability of biopharmaceutical companies may be affected by the continuing efforts of government and third party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. In addition, in the United States and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability and adequacy of reimbursement from third party payers, such as the government or private insurance plans. Third party payers are increasingly challenging established prices, and new products that are more expensive than existing treatments may have difficulty finding ready acceptance unless there is a clear therapeutic benefit. We cannot assure you that any of our products will be considered cost effective, or that reimbursement will be available or sufficient to allow us to sell them competitively and profitably.

We are also subject to various federal, state, and international laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Federal and state false claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on us, including our stock price. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, which could have a materially adverse effect on our business, results of operations and financial condition. We will consult counsel concerning the potential application of these and other laws to our business and our sales, marketing and other activities and will make good faith efforts to comply with them. However, given their broad reach and the increasing attention given by law enforcement authorities, we cannot assure you that some of our activities will not be challenged or deemed to violate some of these laws.

We are also subject to numerous federal, state, local, and international laws and regulations relating to safe working conditions, manufacturing practices, environmental protection, import and export controls, fire hazard control, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances. We believe that our procedures comply with the standards prescribed by federal, state, or local laws, rules, and/or regulations; however, the risk of injury or accidental contamination cannot be completely eliminated. Currently, we have no costs with respect to environmental law compliance. At our current stage of product development, we cannot accurately estimate what our future costs relating to environmental law compliance may be.

We have currently received no approvals from the FDA or other foreign regulators in connection with our product candidates. We intend to file for regulatory approval of our first human clinical trial of CTP-modified hGH during 2009.

Employees

We currently employ 13 full-time and two part-time employees, including six with Ph.D. degrees and three with M.Sc. degrees, focused on research and development, and three focused on general management and business development. None of our employees is represented by a labor union, and we consider our employee relations to be good. We also utilize a number of consultants to assist with research and development and commercialization activities. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel.

Item 1A. Risk Factors

Risks Related to Our Company and Our Business

We have had no operating history as a biopharmaceutical company.

As a company, we have no operating history in our contemplated biopharmaceutical business and, to date, our revenues have been insignificant. Accordingly, it may be difficult to evaluate our business prospects. Moreover, our prospects must be considered in light of the risks and uncertainties encountered by an early-stage company and in highly regulated and competitive markets, such as the biopharmaceutical market, where regulatory approval and market acceptance of our products are uncertain.

We depend on the implementation of our business plan, including our ability to make future investments. There can be no assurance that our efforts will ultimately be successful or result in revenues or profits.

We have not yet commercialized any products or technologies, and we may never become profitable.

We have not yet commercialized any products or technologies, and we may never be able to do so. We do not know when or if we will complete any of our product development efforts, obtain regulatory approval for any product candidates (*i.e.*, potential products) incorporating our technologies, or successfully commercialize any approved products. Even if we are successful in developing products that are approved for marketing, we will not be successful unless these products gain market acceptance. The degree of market acceptance of these products will depend on a number of factors, including:

- the timing of regulatory approvals in the countries, and for the uses, we seek;
- the competitive environment;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products;
- the adequacy and success of distribution, sales and marketing efforts; and
- the pricing and reimbursement policies of government and third-party payors, such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, third-party payors or the medical community in general may be unwilling to accept, utilize or recommend any of our products or products incorporating our technologies. As a result, we are unable to predict the extent of future losses or the time required to achieve profitability, if at all. Even if we successfully develop one or more products that incorporate our technologies, we may not become profitable.

Our product candidates are at an early stage of product development and may never be commercialized.

All of our product candidates are at early stages of product development and may never be commercialized. Initially, we plan to develop product candidates through studies, testing and clinical lead product candidate selection, and then to license them to other companies. The progress and results of any future pre-clinical testing or future clinical trials are uncertain, and the failure of our product candidates to receive regulatory approvals will have a material adverse effect on our business, operating results and financial condition to the extent we are unable to commercialize any products. None of our product candidates has received regulatory approval for commercial sale. In addition, all of our product candidates are in the early stages of development, and we face the risks of failure inherent in developing therapeutic proteins based on new technologies. Our product candidates are not expected to be commercially available for several years, if at all. Although our current plan is to file for regulatory approval of our first human clinical trial of CTP-modified hGH during 2009, our inability to achieve intermediate milestones may negatively impact the expected time period.

In addition, our product candidates must satisfy rigorous standards of safety and efficacy before they can be approved by the FDA and international regulatory authorities for commercial use. The FDA and foreign regulatory

authorities have full discretion over this approval process. We will need to conduct significant additional research, involving testing in animals and in humans, before we can file applications for product approval. Typically, in the pharmaceutical industry there is a high rate of attrition for product candidates in pre-clinical testing and clinical trials. Also, satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. For example, a number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials and in interim analyses. In addition, delays or rejections may be encountered based upon additional government regulation, including any changes in FDA policy, during the process of product development, clinical trials and regulatory approvals.

In order to receive FDA approval or approval from foreign regulatory authorities to market a product candidate or to distribute our products, we must demonstrate through pre-clinical testing and through human clinical trials that the product candidate is safe and effective for the treatment of a specific condition. We do not know when, if ever, any human clinical trials will begin with respect to our product candidates.

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

Even if regulatory authorities approve our product candidates, they may not be commercially successful. Our product candidates may not be commercially successful because physicians, government agencies and other third-party payors may not accept them. Third parties may develop superior products or have proprietary rights that preclude us from marketing our products. We also expect that most of our product candidates will be very expensive, if approved. Patient acceptance of and demand for any product candidates for which we obtain regulatory approval or license will depend largely on many factors, including but not limited to the extent, if any, of reimbursement of therapeutic protein and treatment costs by government agencies and other third-party payors, pricing, the effectiveness of our marketing and distribution efforts, the safety and effectiveness of alternative products, and the prevalence and severity of side effects associated with our products. If physicians, government agencies and other third-party payors do not accept our products, we will not be able to generate significant revenue.

It is highly likely that we will need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute current stockholders' ownership interests.

Our income from operations is unlikely to be sufficient to achieve our business plan. We may need to raise additional funds through public or private debt or equity financings to meet various objectives including, but not limited to:

- pursuing growth opportunities, including more rapid expansion;
- acquiring complementary businesses;
- making capital improvements to improve our infrastructure;
- hiring qualified management and key employees;
- research and development of new products;
- responding to competitive pressures;
- complying with regulatory requirements such as licensing and registration; and
- maintaining compliance with applicable laws.

Any additional capital raised through the sale of equity or equity backed securities may dilute current stockholders' ownership percentages and could also result in a decrease in the fair market value of our equity securities because our assets would be owned by a larger pool of outstanding equity. The terms of those securities issued by us in future capital

transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect.

Furthermore, any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all. If we are unable to obtain required additional capital, we may have to curtail our growth plans or cut back on existing business and, further, we may not be able to continue operating if we do not generate sufficient revenues from operations needed to stay in business.

We may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

If we fail to obtain necessary funds for our operations, we will be unable to maintain and improve our patented technology and we will be unable to develop and commercialize our products and technologies.

Our operations are currently funded primarily through the proceeds from the private offering of our securities in connection with the merger and other private placements. We believe that our existing cash, cash equivalents and financing arrangements should be sufficient to meet our operating and capital requirements for approximately 24 months, although 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 research and development investment required to develop our product candidates, and maintain and improve our patented technology position;
- the costs of obtaining or manufacturing therapeutic proteins for research and development and at commercial scale;
- the results of preclinical and clinical testing, which can be unpredictable in therapeutic protein development;
- changes in product candidate 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 investigating patents that might block us from developing potential product candidates;
- the costs of recruiting and retaining qualified personnel;
- the time and costs involved in obtaining regulatory approvals;
- the costs of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights; and
- our need or decision to acquire or license complementary technologies or new therapeutic protein targets.

We depend on key members of our management and advisory team and will need to add and retain additional leading experts.

We are highly dependent on our executive officers and other key management and technical personnel. If we fail to retain our Chief Executive Officer, Abraham (Avri) Havron, or our President, Shai Novik, or any other key management and technical personnel, this could have a material adverse effect on our future operations. Our success is also dependent on our

ability to attract, retain and motivate highly trained technical, marketing, sales and management personnel, among others, to produce our product candidates and, if our product candidates are produced, to market our products and to continue to produce enhanced releases of our products. We presently do not maintain “key person” life insurance policies on any of our personnel.

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

Under current United States 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 into 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 current United States and Israeli law, we may be unable to enforce these agreements, and it may be difficult for us to restrict our competitors from gaining the expertise our former employees gained while working for us. If we cannot enforce our non-compete agreements with our employees, we may be unable to prevent our competitors from benefiting from the expertise of our former employees, which could have an adverse effect on our ability to capitalize on our proprietary information.

We do not currently have sales, marketing and distribution capabilities, and may be unable to effectively sell, market and distribute our product candidates in the future, and the failure to do so will have an adverse effect on our business and results of operations.

If we are unable to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will not be able to successfully commercialize any of our product candidates. We currently have only limited sales, marketing or distribution capabilities. In order to successfully commercialize any of our product candidates, we must either internally develop sales, marketing and distribution capabilities or make arrangements with third parties to perform these services.

If we do not develop a marketing and sales force with technical expertise and supporting distribution capabilities, we will be unable to market any of our product candidates directly. To promote any of our potential products through third parties, we will have to locate acceptable third parties for these functions and enter into agreements with them on acceptable terms and we may not be able to do so. In addition, any third-party arrangements we are able to enter into may result in lower revenues than we could achieve by directly marketing and selling our potential products.

We may suffer losses from product liability claims if our product candidates cause harm to patients.

Any of our product candidates could cause adverse events, such as immunologic or allergic reactions. These reactions may not be observed in clinical trials, but may nonetheless occur after commercialization. If any of these reactions occur, they may render our product candidates ineffective or harmful in some patients and our sales would suffer, adversely affecting our financial condition.

In addition, potential adverse events caused by our product candidates could lead to product liability lawsuits. If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability claims. Product liability insurance for the pharmaceutical and biotechnology industries is generally expensive, if available at all. We do not currently have any product liability insurance because we are not yet conducting trials on humans. When we begin human trials, we will endeavor to obtain sufficient product liability insurance. If we are unable to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to commercialize our product candidates. A successful product liability claim brought against us in excess of our insurance coverage, if any, may cause us to incur substantial liabilities and, as a result, our business may not succeed.

Our product candidates will remain subject to ongoing regulatory requirements even if they receive marketing approval, and if we fail to comply with these requirements, we could lose these approvals, and the sales of any approved commercial products could be suspended.

Even if we receive regulatory approval to market a particular product candidate, the product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the uses for which the product may be marketed or the conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, which could negatively impact us or our collaboration partners by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. In addition, as clinical experience with a drug expands after approval, typically because it is used by a greater number and more diverse group of patients after approval than during clinical trials, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials or other studies. Any adverse effects observed after the approval and marketing of a product candidate could result in limitations on the use of or withdrawal of any approved products from the marketplace. Absence of long-term safety data may also limit the approved uses of our products, if any. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including the following:

- Restrictions on the products, manufacturers or manufacturing process;
- Warning letters;
- Civil or criminal penalties, fines and/or injunctions;
- Product seizures or detentions;
- Import or export bans or restrictions;
- Voluntary or mandatory product recalls and related publicity requirements;
- Suspension or withdrawal of regulatory approvals;
- Total or partial suspension of production, and
- Refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

If we or our collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, marketing approval for our product candidates may be lost or cease to be achievable, resulting in decreased revenue from milestones, product sales or royalties, which would have a material adverse effect on our results of operations.

Clinical trials are very expensive, time-consuming and difficult to design and implement and, as a result, we may suffer delays or suspensions in future trials which would have a material adverse effect on our ability to generate revenues.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming and while we are optimistic about our ability to complete our clinical trials relatively quickly as compared to average trial lengths for clinical trials, failure can occur at any stage of the trials, and we may encounter problems that cause it to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;

- determination of dosing issues;
- lack of effectiveness or efficacy during clinical trials;
- failure of third party suppliers to perform final manufacturing steps for the drug substance;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and
- lack of sufficient funding to finance the clinical trials.

In addition, we or regulatory authorities may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the regulatory authorities find deficiencies in our regulatory submissions or the conduct of these trials. Any suspension of clinical trials will delay possible regulatory approval, if any, and adversely impact our ability to develop products and generate revenue.

The manufacture of our product candidates is an exacting and complex process, and if we or one of our materials suppliers encounters problems manufacturing its products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with requirements that the FDA or foreign regulators establish. We or our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Drug manufacturers are subject to ongoing periodic unannounced inspections by the FDA, the U.S. Drug Enforcement Agency and corresponding foreign regulators to ensure strict compliance with requirements and other governmental regulations and corresponding foreign standards. Any failure to comply with requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our product candidates.

We may rely on third parties to implement our manufacturing and supply strategies.

If our current and future licensing, manufacturing and supply strategies are unsuccessful, then we may be unable to complete any future pre-clinical or clinical trials and/or commercialize our product candidates in a timely manner, if at all. Completion of any potential future pre-clinical trials and commercialization of our product candidates will require access to, or development of, facilities to manufacture a sufficient supply of our product candidates, or the ability to license them to other companies to perform these functions. We do not have the resources, facilities or experience to manufacture our product candidates on our own and do not intend to develop or acquire facilities for the manufacture of product candidates for pre-clinical trials, clinical trials or commercial purposes in the foreseeable future. We intend to continue to license technology and/or rely on contract manufacturers to produce sufficient quantities of our product candidates necessary for any pre-clinical or clinical testing we undertake in the future. Such contract manufacturers may be the sole source of production and may have limited experience at manufacturing, formulating, analyzing, filling and finishing our types of product candidates.

We also intend to rely on third parties to supply the components that we will need to develop, test and commercialize all of our product candidates. There may be a limited supply of these components. We might not be able to enter into agreements that provide us assurance of availability of such components in the future from any supplier. Our potential suppliers may not be able to adequately supply us with the components necessary to successfully conduct our pre-clinical and clinical trials and/or to commercialize our product candidates. If we cannot acquire an acceptable supply of components to produce our product candidates, we will not be able to complete pre-clinical and clinical trials and will not be able to commercialize our product candidates.

If we make technology or product acquisitions, we may incur a number of costs, may have integration difficulties and may experience other risks that could harm our business and results of operations.

We may acquire and/or license additional product candidates and/or technologies. Any product candidate or technology we license or acquire will likely require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities, if any. All product candidates are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate or product developed based on licensed technology will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any product candidate that we develop based on acquired or licensed technology that is granted regulatory approval will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace. Moreover, integrating any newly acquired product candidates could be expensive and time-consuming. If we cannot effectively manage these aspects of our business strategy, our business may not succeed.

Furthermore, proposing, negotiating and implementing an economically viable acquisition or license can be a lengthy, costly and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition or license of product candidates and/or technologies. We may not be able to acquire the rights to alternative product candidates and/or technologies on terms that we find acceptable, or at all. Our failure to acquire or license alternative product candidates and/or technologies could have a material adverse effect on our business, prospects and financial condition.

We may not be able to successfully grow and expand our business.

We may not be able to successfully expand. Successful implementation of our business plan will require management of growth, which will result in an increase in the level of responsibility for management personnel. To manage growth effectively, we will be required to continue to implement and improve our operating and financial systems and controls to expand, train and manage our employee base. The management, systems and controls currently in place or to be implemented may not be adequate for such growth, and the steps taken to hire personnel and to improve such systems and controls might not be sufficient. If we are unable to manage our growth effectively, it will have a material adverse effect on our business, results of operations and financial condition.

We may encounter difficulties in managing our growth. These difficulties could increase our losses.

We may experience rapid and substantial growth in order to achieve our operating plans, which will place a strain on our human and capital resources. If we are unable to manage this growth effectively, our losses could increase. Our ability to manage our operations and growth effectively requires us to continue to expend funds to enhance our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. If we are unable to scale up and implement improvements to our control systems in an efficient or timely manner, or if we encounter deficiencies in existing systems and controls, then we will not be able to make available the products required to successfully commercialize our technology. Failure to attract and retain sufficient numbers of talented employees will further strain our human resources and could impede our growth or result in ineffective growth.

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

We may not be able to obtain insurance policies on terms affordable to us that would adequately insure our business and property against damage, loss or claims by third parties. To the extent our business or property suffers any damages, losses or claims by third parties, which are not covered or adequately covered by insurance, our financial condition may be materially adversely affected.

We may be unable to maintain sufficient insurance as a public company to cover liability claims made against our officers and directors. If we are unable to adequately insure our officers and directors, we may not be able to retain or recruit qualified officers and directors to manage the Company.

Compliance with the reporting requirements of federal securities laws can be expensive.

We are a public reporting company in the United States and, accordingly, subject to the information and reporting requirements of the U.S. securities laws. The U.S. securities laws require, among other things, review, audit and public reporting of our financial results, business activities and other matters. Recent SEC regulation, including regulation enacted as a result of the Sarbanes-Oxley Act of 2002, has also substantially increased the accounting, legal and other costs related to becoming and remaining an SEC reporting company. The public company costs of preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders will cause our expenses to be higher than they would have been if Modigene Delaware had remained privately-held and did not consummate the merger. These increased costs may be material and may include the hiring of additional employees and/or the retention of additional advisors and professionals. Our failure to comply with the federal securities laws could result in private or governmental legal action against us and/or our officers and directors, which could have a detrimental effect on our business and finances, the value of our stock and the ability of stockholders to resell their stock.

Rules applicable to publicly held companies, including those contained in and issued under the Sarbanes-Oxley Act of 2002, may make it difficult for us to retain or attract qualified officers and directors, which could adversely affect the management of our business and our ability to obtain or retain listing of our common stock.

We may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for our effective management because of the rules and regulations that govern publicly held companies, including, but not limited to, certifications by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these recent changes may deter qualified individuals from accepting roles as directors and executive officers.

Further, some of these rules and regulations heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the corporation and level of experience in finance and accounting matters. We may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business and our ability to obtain or retain listing of our shares of common stock on any stock exchange could be adversely affected.

We are a holding company that depends on cash flow from our wholly-owned subsidiary, to meet our obligations.

We are a holding company with no material assets other than the stock of our wholly-owned subsidiary. Accordingly, all our operations are conducted by Modigene Delaware, our wholly-owned subsidiary (and its wholly-owned subsidiary, ModigeneTech). We currently expect that the earnings and cash flow of our subsidiary will primarily be retained and used by it in its operations, including servicing any debt obligations it may have now or in the future. Accordingly, although we do not anticipate paying any dividends in the foreseeable future, our subsidiary may not be able to generate sufficient cash flow to distribute funds to us in order to allow us to pay future dividends on, or make any distributions with respect to our common stock.

We may have liabilities arising from our prior business.

Prior to the merger, our business involved providing advertising and graphic design services to corporate clients. Pursuant to the merger, we acquired the business of Modigene Delaware and continued the business operations of Modigene Delaware as a publicly-traded company, and accordingly are not pursuing our prior business. Although Modigene Delaware and its legal counsel conducted due diligence on our prior business, the due diligence process may not have revealed all material liabilities of our prior business then existing or that may be asserted in the future against us relating to our activities prior to the consummation of the merger. These liabilities may arise from our prior operating activities (such as employee or labor matters), financing and credit arrangements and other commercial transactions. The merger agreement contains a limited post-closing adjustment to the number of shares of our common stock issued to pre-merger Modigene Delaware stockholders as a means of providing a remedy for breaches of representations made in the merger agreement by us, including representations related to undisclosed liabilities; however, there is no comparable protection offered to our other investors. Any such liabilities that may survive the merger could harm our revenues, business, prospects, financial condition and results of operations upon our acceptance of responsibility for such liabilities. Even if any asserted claims are without merit and we were ultimately found to have no liability for such claims, the defense costs and distraction of management's attention may harm the growth and profitability of our business.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Consequently, investors could lose confidence in our financial reporting and this may decrease the trading price of our stock.

We must maintain effective internal controls to provide reliable financial reports and detect fraud. We have been assessing our internal controls to identify areas that need improvement. As a result of the assessment we have implemented changes to internal controls. Failure to properly maintain our internal controls or any others that we identify as necessary to maintain an effective system of internal controls could harm our operating results and cause investors to lose confidence in our reported financial information. In addition, such failure may cause us to suffer violations of the federal securities laws to the extent we are unable to maintain effective internal controls as a result. Any such loss of confidence or violations would have a negative effect on the trading price of our stock.

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

We maintain office and research and development facilities in the State of Israel. Political, economic and military conditions in Israel may directly affect our ability to conduct business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or a significant downturn in the economic or financial condition of Israel, could affect adversely our operations. Ongoing and revived hostilities or other Israeli political or economic factors could harm our operations and product development and cause our revenues to fail to develop or decrease if we have already begun sales.

Recent disruptions in the financial markets and economic conditions could affect our ability to raise capital and could disrupt or delay the performance of our third-party contractors and suppliers.

In the past year, the U.S. and global economies have taken a dramatic downturn as the result of the deterioration in the credit markets and related financial crisis as well as a variety of other factors including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. The U.S. and certain foreign governments have recently taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If the actions taken by these governments are not successful, the continued economic decline may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all. In addition, we rely and intend to rely on third-parties, including our clinical research organizations, third-party manufacturers and second source suppliers, and certain other important vendors and consultants. As a result of the current volatile and unpredictable global economic situation, there may be a disruption or delay in the performance of our third-party contractors and suppliers. If such third-parties are unable to satisfy their contractual commitments to us, our business could be severely adversely affected.

Risks Related to Our Intellectual Property

We license our core technology from Washington University, and we could lose our rights to this license if a dispute with Washington University arises or if we fail to comply with the financial and other terms of the license.

Modigene Delaware licenses our core intellectual property from Washington University. ModigeneTech initially entered into a non-exclusive license agreement with Washington University in 2001, and in 2004 amended such license agreement to extend the CTP technology to eleven therapeutic proteins and make such license exclusive. In February 2007, Washington University and Modigene Delaware entered into a revised and expanded definitive license agreement (the "License Agreement") pursuant to which we and Washington University expanded the exclusive license, adding additional patents, and expanding the applicability of licensed CTP technology to all proteins and peptides having a native or non-native amino acid sequence, excluding Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), Thyroid Stimulating Hormone (TSH) and Chorionic Gonadotropin (hCG). The License Agreement imposes certain payment, reporting, confidentiality and other obligations on us. In the event that we were to breach any of the obligations and fail to cure, Washington University would have the right to terminate the License Agreement upon 90 days' notice. In addition, Washington University has the right to terminate the License Agreement upon the bankruptcy or receivership of our Company. The termination of the License Agreement would be detrimental to our business, as all of our current product candidates are partly based on the licensed intellectual property. If any dispute arises with respect to our arrangement with Washington University, such dispute may disrupt our operations and would likely have a material and adverse impact on us if resolved in a manner that is unfavorable to our Company.

The failure to obtain or maintain patents, licensing agreements and other intellectual property could impact our ability to compete effectively.

To compete effectively, we need to develop and maintain a proprietary position with regard to our own technologies, intellectual property, licensing agreements, product candidates and business. Legal standards relating to the validity and scope of claims in the CTP technology field are still evolving. Therefore, the degree of future protection for our proprietary rights in our core technologies and any products that might be made using these technologies is also uncertain. The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- while the patents we license have been issued, the pending patent applications we have filed may not result in issued patents or may take longer than we expect to result in issued patents;
- we may be subject to interference proceedings;
- we may be subject to opposition proceedings in foreign countries;
- any patents that are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other companies may challenge patents licensed or issued to us or our customers;
- other companies may independently develop similar or alternative technologies, or duplicate our technologies;
- other companies may design around technologies we have licensed or developed; and
- enforcement of patents is complex, uncertain and expensive.

We cannot be certain that patents will be issued as a result of any of our pending applications, and we cannot be certain that any of our issued patents, whether issued pursuant to our pending applications or licensed from Washington University, will give us adequate protection from competing products. For example, issued patents, including the patents licensed from Washington University, may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope. In addition, since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions.

It is also possible that others may obtain issued patents that could prevent us from commercializing our products or require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business. As to those patents that we have licensed, our rights depend on maintaining our obligations to the licensor under the applicable license agreement, and we may be unable to do so.

In addition to patents and patent applications, we depend upon trade secrets and proprietary know-how to protect our proprietary technology. We require our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information to any other parties. We require our employees and consultants to disclose and assign to us their ideas, developments, discoveries and inventions. These agreements may not, however, provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure.

Costly litigation may be necessary to protect our intellectual property rights and we may be subject to claims alleging the violation of the intellectual property rights of others.

We may face significant expense and liability as a result of litigation or other proceedings relating to patents and other intellectual property rights of others. In the event that another party has also filed a patent application or been issued a patent relating to an invention or technology claimed by us in pending applications, we may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention, which could

result in substantial uncertainties and costs for us, even if the eventual outcome were favorable to us. We, or our licensors, also could be required to participate in interference proceedings involving issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require us to cease using the technology or to license rights from prevailing third parties.

The cost to us of any patent litigation or other proceeding relating to our licensed patents or patent applications, even if resolved in our favor, could be substantial. Our ability to enforce our patent protection could be limited by our financial resources, and may be subject to lengthy delays. If we are unable to effectively enforce our proprietary rights, or if we are found to infringe the rights of others, we may be in breach of our License Agreement.

A third party may claim that we are using inventions claimed by their patents and may go to court to stop us from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume time and other resources. There is a risk that the court will decide that we are infringing the third party's patents and will order us to stop the activities claimed by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having infringed their patents.

Moreover, there is no guarantee that any prevailing patent owner would offer us a license so that we could continue to engage in activities claimed by the patent, or that such a license, if made available to us, could be acquired on commercially acceptable terms. In addition, third parties may, in the future, assert other intellectual property infringement claims against us with respect to our product candidates, technologies or other matters.

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

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

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

International patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries, we may have to expend substantial sums and management resources.

Patent law outside the United States is even more uncertain than in the United States and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. For example, certain countries do not grant patent claims that are directed to the treatment of humans. We may participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts.

We may be unable to protect the intellectual property rights of the third parties from whom we license certain of our intellectual property or with whom we have entered into other strategic relationships.

Certain of our intellectual property rights are currently licensed from Washington University and, in the future, we intend to continue to license intellectual property from Washington University and/or other key strategic partners. We are, and will continue to be, reliant upon such third parties to protect their intellectual property rights to any licensed technology. Such third parties may determine not to protect the intellectual property rights that we license from them and we may be unable to defend such intellectual property rights on our own or we may have to undertake costly litigation to defend the intellectual property rights of such third parties. There can be no assurances that we will continue to have proprietary rights to any of the intellectual property that we license from such third parties or otherwise have the right to use through similar strategic relationships. Any loss or limitations on use with respect to our right to use such intellectual property licensed from third parties or otherwise obtained from third parties with whom we have entered into strategic relationships could have a material adverse effect on our business, operating results and financial condition.

Risks Related to Our Industry

We are subject to government regulations, and we may experience delays in obtaining required regulatory approvals in the United States to market our proposed product candidates.

Various aspects of our operations are or may become subject to federal, state or local laws, rules and regulations, any of which may change from time to time. Costs arising out of any regulatory developments could be time-consuming, expensive and could divert management resources and attention and, consequently, could adversely affect our business operations and financial performance.

Delays in regulatory approval, limitations in regulatory approval and withdrawals of regulatory approval may have a negative impact on our results. If we experience significant delays in testing or approvals, our product development costs, or our ability to license product candidates, will increase. If the FDA grants regulatory approval of a product, this approval will be limited to those disease states and conditions for which the product has demonstrated, through clinical trials, to be safe and effective. Any product approvals that we receive in the future could also include significant restrictions on the use or marketing of our products. Product approvals, if granted, can be withdrawn for failure to comply with regulatory requirements or upon the occurrence of adverse events following commercial introduction of the products. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us. If approval is withdrawn for a product, or if a product were seized or recalled, we would be unable to sell or license that product and our revenues would suffer. In addition, outside the United States, our ability to market any of our potential products is contingent upon receiving market application authorizations from the appropriate regulatory authorities and these foreign regulatory approval processes include all of the risks associated with the FDA approval process described above.

We face significant competition and continuous technological change.

If our competitors develop and commercialize products faster than we do, or develop and commercialize products that are superior to our product candidates, our commercial opportunities will be reduced or eliminated. The extent to which any of our product candidates achieve market acceptance will depend on competitive factors, many of which are beyond our control. Competition in the pharmaceutical industry is intense and has been accentuated by the rapid pace of technology development. Our competitors include large integrated pharmaceutical companies, biotechnology companies that currently have drug and target discovery efforts, universities, and public and private research institutions. Almost all of these entities have substantially greater research and development capabilities and financial, scientific, manufacturing, marketing and sales resources than we do, as well as more experience in research and development, clinical trials, regulatory matters, manufacturing, marketing and sales. These organizations also compete with us to:

- attract parties for acquisitions, joint ventures or other collaborations;
- license proprietary technology that is competitive with the technology we are developing;
- attract funding; and

- attract and hire scientific talent.

Our competitors may succeed in developing and commercializing products earlier and obtaining regulatory approvals from the FDA more rapidly than we do. Our competitors may also develop products or technologies that are superior to those we are developing, and render our product candidates or technologies obsolete or non-competitive. If we cannot successfully compete with new or existing products, our marketing and sales will suffer and we may not ever be profitable.

We expect the healthcare industry to face increased scrutiny over reimbursement and healthcare reform, which could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our products.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third party payors, which include government health administration authorities, managed care providers and private health insurers. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Increasing expenditures for healthcare have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the U.S. healthcare system have been introduced or proposed in Congress and in some state legislatures, including reductions in the cost of prescription products and changes in the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products. Although we cannot predict the full effect on our business of the implementation of any legislation, we believe that legislation that reduces reimbursement for our products could adversely impact how much or under what circumstances healthcare 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 are subject to federal anti-kickback laws and regulations. Our failure to comply with these laws and regulations could have adverse consequences to us.

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the anti-kickback statute, which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs; and the Civil Monetary Penalties Law, which authorizes the United States Department of Health and Human Services to impose civil penalties administratively for fraudulent or abusive acts.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. An investigation into the use by physicians of any of our products once commercialized may dissuade physicians from either purchasing or using them, and could have a material adverse effect on our ability to commercialize those products.

Risks Related to Our Securities

Our common stock has a limited trading history and prospective investors may not be able to sell their shares at their purchase price, if at all.

There is currently a limited public market for our common stock. Our common stock is currently quoted on FINRA's OTC Bulletin Board under the symbol "MODG.OB." Prior to our merger with Modigene Delaware, there was no trading of our common stock, and there is no assurance that a regular trading market will develop or, if developed, will be sustained. As a result, an investor may find it difficult to dispose of, or to obtain accurate quotations of the price of, our common stock.

We expect the market price of our common stock will fluctuate significantly in response to factors, some of which are beyond our control, such as the announcement of new products or product enhancements by us or our competitors, developments concerning intellectual property rights and regulatory approvals, quarterly variations in our and our competitors' results of operations, changes in earnings estimates or recommendations by securities analysts, developments in our industry, and general market conditions and other factors, including factors unrelated to our own operating performance or the condition or prospects of our industry.

We cannot assure you that our common stock will become liquid or that it will be listed on a securities exchange.

We may seek listing of our common stock on the NYSE Alternext US (formerly the American Stock Exchange) or the Nasdaq Stock Market. However, we cannot assure you that we will be able to meet the initial listing standards of either of those or of any other stock exchange, or that we will be able to maintain any such listing. Until the common stock is listed on an exchange, we expect to remain eligible for quotation on the OTC Bulletin Board, or on another over-the-counter quotation system, or in the "pink sheets." In those venues, however, an investor may find it difficult to obtain accurate quotations as to the market value of the common stock. In addition, if we fail to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect the liquidity of our common stock. This would also make it more difficult for us to raise additional capital or attract qualified employees or partners.

Further, the stock market in general, and securities of small-cap companies in particular, have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. You should also be aware that price volatility might be worse if the trading volume of the common stock is low.

Applicable SEC rules governing the trading of "penny stocks" limits the trading and liquidity of our common stock which may affect the trading price of our common stock.

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to specific exemptions. The market price of our common stock is currently less than \$5.00 per share and therefore is designated as a "penny stock" according to SEC rules. This designation requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell the common stock and may affect the ability of investors to sell their shares. In addition, since our common stock is currently traded on the OTC Bulletin Board, investors may find it difficult to obtain accurate quotations of our common stock and may experience a lack of buyers to purchase such stock or a lack of market makers to support the stock price.

The price of our common stock may become volatile, which could lead to losses by investors and costly securities litigation.

The trading price of our common stock is likely to be highly volatile and could fluctuate in response to factors such as:

- 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;
- sales of our common stock or other securities in the open market; and
- other events or factors, many of which are beyond our control.

The stock market has experienced significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against the company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

We do not anticipate dividends to be paid on our common stock, and investors may lose the entire amount of their investment.

Cash dividends have never been declared or paid on our common stock, and we do not anticipate such a declaration or payment for the foreseeable future. We expect to use future earnings, if any, to fund business growth. Therefore, stockholders will not receive any funds absent a sale of their shares. We cannot assure stockholders of a positive return on their investment when they sell their shares, nor can we assure that stockholders will not lose the entire amount of their investment.

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 common stock will depend 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 common stock. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect its market price. If we are covered by securities analysts, and our stock is the subject of an unfavorable report, our stock price 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 or trading volume to decline. In addition, because we became public through a "reverse merger," we may have further difficulty attracting the coverage of securities analysts.

Stockholders may experience dilution of ownership interests because of the future issuance of additional shares of our common stock and our preferred stock.

In the future, we may issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present stockholders. We are currently authorized to issue an aggregate of 310,000,000 shares of capital stock consisting of 300,000,000 shares of common stock and 10,000,000 shares of preferred stock with preferences and rights to be determined by our Board of Directors. As of March 10, 2009, there were 35,549,028 shares of our common stock outstanding and a total of 8,788,848 shares subject to outstanding options and warrants. On March 25, 2008, we authorized and issued 800,000 shares of preferred stock designated as Series A preferred stock, and we have reserved a total of 4,000,000 shares of our common stock for issuance upon conversion of the Series A preferred stock. Under a line of credit agreement entered into on March 25, 2008, we may become obligated to issue warrants exercisable for an additional 1,500,000 shares of our common stock if we draw on or extend the line of credit. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for common stock in connection with hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of our common stock may create downward pressure on the trading price of the common stock. There can be no assurance that we will not be required to issue additional shares, warrants

or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock are currently traded on the OTC Bulletin Board.

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

Our officers, directors, principal stockholders and their affiliates control approximately 35.7% of our outstanding common stock. If these stockholders act together, they will be able to exert significant control over our management and affairs requiring stockholder approval, including approval of significant corporate transactions. 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. This concentration of ownership may not be in the best interests of all our stockholders. Holders of our common stock have no effective voice in the management of the Company. Sales by insiders or affiliates of the Company, along with any other market transactions, could affect the market price of our common stock.

A significant number of our shares are eligible for sale, which could depress the market price of our stock.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our stock. As additional shares of our common stock become available for resale in the public market, the supply of the common stock will increase, which could decrease its price. Further, shares may be offered from time to time in the open market pursuant to Rule 144, and these sales may have a depressive effect on the market for the shares of our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our executive offices and our research and development laboratory are located at 3 Sapir Street, Weizmann Science Park, Nes-Ziona, Israel 74140 and our phone number is (866) 644-7811. The facility is approximately 6,000 square feet. We pay a monthly lease of \$7,600, plus approximately \$450 per month with respect to taxes and utilities, for this space. This lease will expire on January 20, 2012.

Item 3. Legal Proceedings

From time to time we may be named in claims arising in the ordinary course of business. Currently, no legal proceedings, government actions, administrative actions, investigations or claims are pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition.

Item 4. Submission of Matters to a Vote of Security Holders

None.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is currently available for trading in the over-the-counter market and is quoted on the OTC Bulletin Board under the symbol “MODG.OB.”

Prior to our merger with Modigene Delaware, there was no bid history for our common stock, because it had never been publicly traded. For the periods indicated, the following table sets forth the high and low bid prices per share of common stock, as reported on the OTC Bulletin Board:

Quarter Ended	High Bid	Low Bid
December 31, 2008	\$ 3.50	\$ 0.37
September 30, 2008	\$ 3.50	\$ 0.80
June 30, 2008	\$ 6.00	\$ 0.65
March 31, 2008	\$ 8.00	\$ 0.80
December 31, 2007	\$ 8.50	\$ 0.60
September 30, 2007	\$ 3.25	\$ 1.34
June 30, 2007	\$ 4.25	\$ 0.00

The over-the-counter market quotations provided above reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

Number of Holders

As of March 10, 2009, the Company’s common stock was held by 92 stockholders of record.

Dividends

The Company has never declared or paid dividends. We do not intend to pay cash dividends on our common stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of dividends if any, on the common stock will rest solely within the discretion of our board of directors and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

Recent Sales of Unregistered Securities

Information regarding any securities sold by the Company (or our predecessor, Modigene Delaware) during the last three years without registering the securities under the Securities Act of 1933, as amended, is included in the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 12, 2007, and the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2008.

Purchases of Equity Securities by the Issuer

None

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation

You should read the following discussion and analysis in conjunction with our financial statements, including the notes thereto, included in this Form 10-K.

As the result of the merger, the private placement offering, the private sale and the split-off, and the change in our business and operations from a design company to a biotechnology company, a discussion of our past financial results prior to the merger is not pertinent, and the financial results of Modigene Delaware, the accounting acquirer, are considered our financial results on a going-forward basis.

Amendment of Financial Statements

On March 31, 2008 The Company filed its Annual Report on Form 10-KSB for the year ended December 31, 2007. On June 13, 2008, the Company received a comment letter from the SEC. As part of the Company's response to the comment letter, three amendments were filed to amend the accounting treatment of the reverse acquisition from purchase accounting to a recapitalization. As discussed in Note 11 to the 2008 annual financial statements filed as Item 8 herewith, on May 9, 2007, Modigene Delaware, Modigene Acquisition Corp. (the acquisition subsidiary of the Company) and the Company, entered into the Merger Agreement. In accordance with Statement of Financial Accounting Standard No. 141, the Company has amended the 2007 annual financial statements. The following 2007 financial statements line items were affected by the restatement:

	<u>Originally reported</u>	<u>Amended</u>	<u>Differences</u>
<u>Balance Sheets:</u>			
Additional paid-in capital	\$ 35,368,596	\$ 24,368,587	\$ 11,000,009
(Deficit) accumulated during the development stage	\$ (23,506,580)	\$ (12,506,571)	\$ (11,000,009)
<u>Statements of Operations:</u>			
<u>For the year ended December 31, 2007:</u>			
In-process research and development write-off	\$ (11,000,009)	\$ -	\$ (11,000,009)
Operating (loss)	\$ (14,666,804)	\$ (3,666,795)	\$ (11,000,009)
Net (loss)	\$ (14,313,212)	\$ (3,313,203)	\$ (11,000,009)
(Loss) per share (basic & diluted)	\$ (0.52)	\$ (0.12)	\$ (0.40)
<u>For the Period from May 31, 2005 (date of inception) to December 31, 2007:</u>			
In-process research and development write-off	\$ (14,222,840)	\$ (3,222,831)	\$ (11,000,009)
Operating (loss)	\$ (23,894,745)	\$ (12,894,736)	\$ (11,000,009)
Net (loss)	\$ (23,506,580)	\$ (12,506,571)	\$ (11,000,009)
(Loss) per share (basic & diluted)	\$ (1.24)	\$ (0.66)	\$ (0.58)
<u>Statement of Stockholders' Equity:</u>			
Additional paid-in capital	\$ 35,368,596	\$ 24,368,587	\$ 11,000,009
(Deficit) accumulated during the development stage	\$ (23,506,580)	\$ (12,506,571)	\$ (11,000,009)
Net (loss)	\$ (14,313,212)	\$ (3,313,203)	\$ (11,000,009)
<u>Statement of Cash Flows:</u>			
<u>For the year ended December 31, 2007:</u>			
Net (loss)	\$ (14,313,212)	\$ (3,313,203)	\$ (11,000,009)
In-process research and development write-off	\$ (11,000,009)	\$ -	\$ (11,000,009)
<u>For the Period from May 31, 2005 (date of inception) to December 31, 2007:</u>			
Net (loss)	\$ (23,506,580)	\$ (12,506,571)	\$ (11,000,009)
In-process research and development write-off	\$ (14,222,840)	\$ (3,222,831)	\$ (11,000,009)

Plan of Operation

During 2009, Modigene intends to continue the development of its preclinical programs, including hGH-CTP, Interefron- β -CTP, and GLP-1-CTP. These programs include a variety of operating tasks such as optimization of expression levels, toxicity and efficacy animal models, completion of purification processes, and GMP production of compounds. The Company's cash resources, including expected payments from the OCS, and its line of credit agreement, are expected to be sufficient to maintain the Company's operations through the fourth quarter of 2010. The Company is not planning any major purchase or sale of equipment during that timeframe, and its employee headcount is expected to increase by five to eighteen employees, of which seventeen will be full time.

Management's Discussion and Analysis

The discussion and analysis of the Company's financial condition and results of operations are based on the Company's financial statements, which the Company has prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, the Company evaluates such estimates and judgments, including those described in greater detail below. The Company bases its estimates on historical experience and on various other factors that the Company believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Results of Operation

Critical Accounting Policies

Financial Statements in United States Dollars: The functional currency of the Company is, and of Modigene Delaware prior to the Merger has been, the U.S. dollar, as the U.S. dollar is the primary currency of the economic environment in which Modigene Delaware has operated and in which the Company expects to continue to operate in the foreseeable future. The majority of ModigeneTech's operations are currently conducted in Israel, and most of the Israeli expenses are paid in new Israeli shekels; however, most of the expenses are denominated and determined in U.S. dollars. Financing and investing activities, including loans and equity transactions, are made in U.S. dollars.

Accordingly, monetary accounts maintained in currencies other than the U.S. dollar are remeasured into U.S. dollars in accordance with Statement No. 52 of the Financial Accounting Standards Board ("FASB"), "Foreign Currency Translation." All transaction gains and losses from the remeasurement of monetary balance sheet items are reflected in the statements of operations as financial income or expenses, as appropriate.

Research and Development Costs and Participation: Research and development ("R&D") costs are expensed as they are incurred and consist of salaries, benefits and other personnel related costs, fees paid to consultants, clinical trials and related clinical manufacturing costs, license and milestone fees, and facilities and overhead costs. R&D expenses consist of independent R&D costs and costs associated with collaborative R&D and in-licensing arrangements. Participation from government for development of approved projects are recognized as a reduction of expenses as the related costs are incurred.

Royalty-bearing Grants: Royalty-bearing grants from the Government of Israel for participation in development of approved projects are recognized as a reduction of expenses as the related costs are incurred. Funding is recognized at the time ModigeneTech is entitled to such grants, on the basis of the costs incurred.

Research and development grants received by ModigeneTech for the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008 amounted to \$865,367, \$272,282, and \$1,237,517, respectively.

Loss per Share: Basic and diluted losses per share are presented in accordance with Statement of Financial Accounting Standard No. 128 "Earning per Share." Outstanding share options and warrants have been excluded from the calculation of the diluted loss per share because all such securities are antidilutive. The total weighted average number of ordinary shares related to outstanding options and warrants excluded from the calculations of diluted loss per share were 7,620,546, 4,871,003 and 4,205,460 for the years ending December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008, respectively.

Revenue

The Company has not generated any substantial revenue since its inception. To date, the Company has funded its operations primarily through grants from the OCS and the sale of equity securities. If the Company's development efforts result in clinical success, regulatory approval and successful commercialization of the Company's products, the Company could generate revenue from sales of its products.

Research and Development Expense

The Company expects its research and development expense to increase as it continues to develop its product candidates. Research and development expense consists of:

- internal costs associated with research and development activities;
- payments made to third party contract research organizations, contract manufacturers, investigative sites, and consultants;
- manufacturing development costs;
- personnel-related expenses, including salaries, benefits, travel, and related costs for the personnel involved in the research and development;
- activities relating to the advancement of product candidates through preclinical studies and clinical trials; and
- facilities and other expenses, which include expenses for rent and maintenance of facilities, as well as laboratory and other supplies.

These costs and expenses are partially funded by grants received by the Company from the OCS. There can be no assurance that the Company will continue to receive grants from the OCS in amounts sufficient for its operations, if at all.

The Company expects its research and development expenditures to increase most significantly in the near future in connection with the ongoing production of its protein drug candidates. The Company intends to continue to hire new employees, in research and development, in order to meet its operation plans.

The Company has multiple research and development projects ongoing at any one time. The Company utilizes its internal resources, employees, and infrastructure across multiple projects and tracks time spent by employees on specific projects. The Company believes that significant investment in product development is a competitive necessity and plans to continue these investments in order to realize the potential of its product candidates. For the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008 the Company incurred a gross research and development expense in the aggregate of \$5,527,102, \$2,667,733, and \$9,060,314, respectively.

The successful development of the Company's product candidates is subject to numerous risks, uncertainties, and other factors. Beyond the next twelve months, the Company cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from the Company's product candidates or any of the Company's other development efforts. This is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials which vary significantly over the life of a project as a result of differences arising during clinical development, including:

- completion of such preclinical and clinical trials;
- receipt of necessary regulatory approvals;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;

- adverse medical events or side effects in treated patients;
- lack of comparability with complementary technologies;
- obtaining capital necessary to fund operations, including the research and development efforts; and
- the results of clinical trials.

The Company's expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. The Company may obtain unexpected results from its clinical trials. The Company may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of the foregoing variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require the Company to conduct clinical trials beyond those which it currently anticipates will be required for the completion of the clinical development of a product candidate, or if the Company experiences significant delays in enrollment in any of its clinical trials, the Company could be required to expend significant additional financial resources and time on the completion of clinical development. Drug development may take several years and millions of dollars in development costs. If the Company does not obtain or maintain regulatory approval for its products, its financial condition and results of operations will be substantially harmed.

General and Administrative Expense

General and administrative expense consists primarily of salaries and other related costs, including stock-based compensation expense, for persons serving in the Company's executive and administration functions. Other general and administrative expense includes facility-related costs not otherwise included in research and development expense, and professional fees for legal and accounting services, including those associated with reporting obligations applicable to public companies in the United States. The Company expects that its general and administrative expenses will increase as it adds additional personnel and advances its research and development programs. For the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008 the Company incurred general and administrative expenses of \$2,410,015, \$1,668,060, and \$9,317,574, respectively.

Financial Expense and Income

Financial expense and income consists of the following:

- interest earned on the Company's cash and cash equivalents;
- interest expense on short term bank credit and loan; and
- expense or income resulting from fluctuations of the New Israeli Shekel, which a portion of the Company's assets and liabilities are denominated in, against the United States Dollar and other foreign currencies.

For the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008 the Company recorded net financial income of \$157,568, \$353,592, and \$545,733 respectively.

Stock-based Compensation

On January 1, 2006, the Company adopted Statement of Financial Accounting Standard No. 123 (revised 2004), "Stock-Based Payment" ("SFAS 123(R)"), which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and directors, including employee stock options under the Company's stock plan, based on estimated fair values. SFAS(R) superseded the Company's previous accounting under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") for periods beginning in fiscal 2006.

SFAS 123(R) requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's consolidated statement of operations. Prior to the adoption of SFAS 123(R), the Company accounted for equity-based awards to employees and directors using the intrinsic value method, in

accordance with APB 25, as allowed under Statement of Financial Accounting Standard No. 123, "Accounting for Stock-Based Compensation ("SFAS 123").

The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006. Under this transition method, compensation cost recognized in the year ended December 31, 2006 includes: (a) compensation cost for all stock-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all stock-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). As required by the modified prospective method, results for prior periods have not been restated.

The Company recognized compensation expenses for the value of these awards, based on the straight line method over the requisite service period of each award.

The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option-pricing model. For the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008 the Company's stock-based compensation expenses were \$1,039,028, \$1,211,536, and \$6,467,444, respectively.

The Company applies SFAS 123 and EITF 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" ("EITF 96-18") with respect to options and warrants issued to non-employees.

SFAS 123 and EITF 96-18 require the use of an option valuation model to measure the fair value of the options at the grant date.

Revenues

There were no revenues for the years ended December 31, 2008 and 2007 or for the period from May 31, 2005 (inception date) through December 31, 2008.

Research and Development Expenses

For the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008, the Company incurred a gross research and development expense in the aggregate of \$5,527,102, \$2,667,733, and \$9,060,314, respectively. The increase resulted primarily from significant development expenses related to non-GMP and GMP production costs associated with the development of hGH-CTP, as well as other development costs associated with IFN-Beta-CTP. The increase for the year ended December 31, 2008 was partially offset by \$746,013 in grant funds received by the Company from the OCS.

General and Administrative Expenses

For the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008, the Company incurred a gross general and administrative expense in the aggregate of \$2,410,015, \$1,668,060, and \$9,317,574, respectively. The increase resulted primarily from stock-based compensation and salary increases.

Financial Expenses and Income

For the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2007, the Company recorded gross financial income of \$157,568, \$353,592, and \$545,733, respectively. The decrease resulted primarily from the lower balance of cash and cash equivalents held by the Company during the 2008, as well as decline in interest rates paid on deposits.

Cash Flows

For the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008, net cash used in operations was approximately \$5,761,061, \$2,649,302, and \$9,859,727, respectively. The increase in 2008 resulted primarily from the increases in R&D expenses and general and administrative expenses.

For the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008, net cash used in investing activities was approximately \$227,628, \$80,801, and \$984,059, respectively.

For the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008, net cash provided by financing activities was approximately \$1,998,114, \$13,400,745, and \$18,309,018, respectively. The decrease in 2008 resulted primarily from the significant reduction in proceeds from issuances of common and/or preferred shares to investors in comparison with 2007.

Funding Requirements

The Company expects to incur losses from operations for the foreseeable future. The Company expects to incur increasing research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. The Company expects that general and administrative expenses will also increase as the Company expands its finance and administrative staff, adds infrastructure, and incurs additional costs related to being a public company in the United States, including the costs of directors' and officers' insurance, investor relations programs, and increased professional fees. Our future capital requirements will depend on a number of factors, including the continued progress of its research and development of product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates.

On March 25, 2008, we entered into a line of credit with The Frost Group, LLC ("TFG"), a Florida limited liability company whose members include Frost Gamma Investments Trust (the "Frost Trust"), Jane Hsiao, M.B.A., Ph.D., and Steven D. Rubin. Dr. Phillip Frost, the Chairman of our board of directors, is the sole trustee of the Frost Trust. Frost Gamma, L.P. is the sole and exclusive beneficiary of the Frost Trust, and Dr. Frost is one of two limited partners of Frost Gamma, L.P. The general partner of Frost Gamma, L.P. is Frost Gamma, Inc. and the sole stockholder of Frost Gamma, Inc. is Frost-Nevada Corporation. Dr. Frost is the sole stockholder of Frost-Nevada Corporation. Dr. Hsiao and Mr. Rubin are also directors of Modigene.

Under this line of credit, we may, at our discretion, borrow up to \$10,000,000, which proceeds may be used for working capital or general corporate purposes, as approved by our board of directors. The maturity date for the line of credit is March 25, 2009, unless (i) we have borrowed any funds under the line of credit prior to March 25, 2009, or (ii) we elect to extend the line of credit. In either of such events, the maturity date will be extended until March 25, 2013. Upon the maturity date, we will be obligated to repay to TFG all outstanding borrowings, together with any accrued interest, and the line of credit will terminate. We will be obligated to pay interest on outstanding borrowings under the line of credit at a 10% annual rate. If we determine to draw on the line of credit, or if we elect to extend the maturity date until March 25, 2013, we will issue to TFG five-year warrants to purchase 1,500,000 shares of our common stock, having an exercise price of \$0.99 per share. We have not borrowed any funds under the line of credit, and do not expect to borrow any funds prior to March 25, 2009. In March 2009, TFG agreed to grant the Company until April 30, 2009 to elect whether to extend the line of credit.

We believe that our existing cash, cash equivalents and the line of credit agreement will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least until December 31, 2009. We have based this estimate on assumptions that may prove to be wrong or subject to change, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of its product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including the progress and results of our clinical trials, the duration and cost of discovery and preclinical development, and laboratory testing and clinical trials for our product candidates, the timing and outcome of regulatory review of our product candidates, the number and development requirements of other product candidates that we pursue, and the costs of commercialization activities, including product marketing, sales, and distribution. We do not anticipate that we will generate product revenues for at least the next several years. In the absence of additional funding, we expect continuing operating losses to result in increases in our cash used in operations over the next several years. To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. We currently do not have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions proves 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 may result in dilution to our shareholders. The incurrence of indebtedness would

result in increased fixed obligations and could also result in covenants that would restrict our operations. Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Effects of Inflation and Currency Fluctuations

Inflation generally affects the Company by increasing its cost of labor and clinical trial costs. The Company does not believe that inflation has had a material effect on its results of operations during the years ended December 31, 2008 and December 31, 2007.

Currency fluctuations could affect the Company by increased or decreased costs mainly for goods and services acquired outside of Israel. The Company does not believe currency fluctuations have had a material effect on its results of operations during the years ended December 31, 2008 and December 31, 2007.

Recently Issued Accounting Pronouncements

In September 2006, the Financial Accounting Standard Board (“FASB”) issued SFAS 157 “Fair Value Measures” (“SFAS 157”). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. In February 2008, the FASB issued FASB Staff Positions (“FSP”) 157-1, which amends SFAS 157 to remove leasing transactions accounted for under SFAS 13, “Accounting for Leases,” FSP 157-2, which deferred the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis to fiscal years beginning after November 15, 2008 and FSP 157-3, which clarifies the application of SFAS 157 in a market that is not active and illustrates considerations in determining the fair value of a financial asset when the market for the financial asset is not active. The Company is currently assessing the impact of SFAS No. 157 and FSP 157-2 and will adopt this standard at the beginning of the fiscal year ending on December 31, 2009. The Company believes the adoption of this pronouncement will not have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160 “Non-controlling Interests in Consolidated Financial Statements—an amendment of ARB No. 51.” SFAS 160 establishes accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. The guidance will become effective as of the beginning of our fiscal year beginning after December 15, 2008. The Company believes the adoption of this pronouncement will not have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141R “Business Combinations (revised 2007).” This statement replaces SFAS 141, “Business Combinations.” The statement provides guidance for how the acquirer recognizes and measures the identifiable assets acquired, liabilities assumed and any non-controlling interest in the acquiree. SFAS 141R provides for how the acquirer recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase. The statement determines what information to disclose to enable users to be able to evaluate the nature and financial effects of the business combination. SFAS 160 is effective for fiscal years beginning after December 15, 2008, and do not allow early adoption. The Company believes the adoption of this pronouncement will not have a material impact on our consolidated financial statements.

In April 2008, the FASB issued FASB Staff Position (FSP) FSP 142-3, “Determination of the Useful Life of Intangible Assets.” This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, “Goodwill and Other Intangible Assets.” The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under Statement 142 and the period of expected cash flows to measure the fair value of the asset under SFAS No. 141R “Business Combinations (revised 2007),” and other U.S. generally accepted accounting principles (GAAP). This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company does not expect the adoption of FAS 142-3 to have a material effect on its results of operations and financial condition.

In May 2008, the FASB issued FASB Staff Position (FSP) No. APB 14-1 “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)”. FSP APB 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account

for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer's non-convertible debt borrowing rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008, on a retroactive basis and will be adopted by the Company in the first quarter of fiscal 2009. The Company does not expect the adoption of FSP APB 14-1 to have a material effect on its results of operations and financial condition.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the Company's financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources that are material to investors.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

See the Index to Consolidated Financial Statements on Page F-1 attached hereto.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A(T). Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, is responsible for evaluating the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by this report. As defined by the rules of the SEC, disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in the reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms and include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Pursuant to this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the end of the period covered by this report.

Management's Annual Report on Internal Control Over Financial Reporting

The information contained in this Management's Annual Report on Internal Control Over Financial Reporting shall not be deemed to be "filed" with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future document filed with the Securities and Exchange Commission, or subject to the liabilities of Section 18 of the Securities Exchange Act, unless and except to the extent that such report is specifically stated to be incorporated by reference into such document.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting. As defined by the rules of the SEC, internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, 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.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our internal control over financial reporting. This evaluation utilized the framework published by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), which was implemented by the Company throughout the year and formally adopted by the Company on September 25, 2008, and was conducted in accordance with the interpretive guidance issued by the SEC in Release No. 34-55929. Our evaluation took into account the Company's receipt and satisfactory resolution during the Company's second and third fiscal quarter of comments received from the SEC regarding the accounting treatment for the Company's acquisition of Modigene Delaware, and the Company's implementation in the third fiscal quarter of enhanced verification procedures for any future merger and acquisition accounting, which procedures are designed to verify that any such accounting is conducted in full alignment with U.S. generally accepted accounting principles. Pursuant to this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that our disclosure internal control over financial reporting was effective at the end of the period covered by this report.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or 15d-15 promulgated under the Exchange Act that occurred during the last fiscal quarter of the fiscal year ended December 31, 2008, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Management is aware that there is a lack of segregation of duties at our company due to the limited number of employees dealing with general administrative and financial matters. At this time management believes that, given the individuals involved and the control procedures in place, the risks associated with such lack of segregation are insignificant, and that the potential benefits of adding additional employees to segregate duties more clearly do not justify the associated added expense. Management will continue to evaluate this segregation of duties. In addition, management is aware that few of our currently existing internal controls are undocumented. Our management will be working to document such internal controls over the coming year.

Item 9B. Other Information

As disclosed above in Item 1 of this Annual Report on Form 10-K, on March 25, 2008, we entered into a line of credit with TFG under which we may, at our discretion, borrow up to \$10,000,000, which proceeds may be used for working capital or general corporate purposes, as approved by our board of directors. The maturity date for the line of credit is March 25, 2009, unless (i) we have borrowed any funds under the line of credit prior to March 25, 2009, or (ii) we elect to extend the line of credit. In either of such events, the maturity date will be extended until March 25, 2013. If we determine to draw on the line of credit, or if we elect to extend the maturity date until March 25, 2013, we will issue to TFG five-year warrants to purchase 1,500,000 shares of our common stock, having an exercise price of \$0.99 per share. We have not borrowed any funds under the line of credit, and do not expect to borrow any funds prior to March 25, 2009. On March 11, 2009, TFG agreed to grant the Company until April 30, 2009 to elect whether to extend the line of credit.

PART III

Item 10, 11, 12, 13 and 14. Directors, Executive Officers and Corporate Governance; Executive Compensation; Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters; Relationships and Related Transactions, and Director Independence; and Principal Accountant Fees and Services

The information required by Item 10, Item 11, Item 12, Item 13 and Item 14 is hereby incorporated or furnished, solely to the extent required by such item, from the Company's definitive Proxy Statement for the Annual Meeting of Stockholders to be held in 2009, a copy of which is expected to be filed with the Securities and Exchange Commission on or before April 20, 2009.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

1. *Financial Statements.* The following Consolidated Financial Statements of Modigene Inc. are included in Item 8 of this Annual Report on Form 10-K:

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2. *Financial Statement Schedule.* Financial statement schedules have been omitted since they are either not required, are not applicable or the required information is shown in the consolidated financial statements or related notes.

3. *Exhibits*

<u>Exhibit No.</u>	<u>Description</u>	<u>Reference</u>
3.1	Amended and Restated Articles of Incorporation of Modigene Inc. (f/k/a LDG, Inc.)	Incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on February 27, 2007.
3.2	Amended and Restated Bylaws of Modigene Inc. (f/k/a LDG, Inc.)	Incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
4.1	Form of Investor Warrant of Modigene Inc. issued as of May 9, 2007	Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
4.2	Form of Warrant of Modigene Inc. issued to broker/dealers as of May 9, 2007	Incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
4.3	Form of Warrant of Modigene Inc. issued to Frost Gamma Investments Trust, Jane Hsiao, Steven D. Rubin and Subbarao Uppaluri	Incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
4.4	Warrant Agreement dated as of May 9, 2007, between Modigene Inc. and Spencer Trask Ventures, Inc., together with the form of Warrant Certificate issued thereunder	Incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
4.5	Form of Lock-Up Agreement	Incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
4.6	Certificate of Designations of Preferences, Rights and Limitations of Series A Convertible Preferred Stock	Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on March 27, 2008.

Exhibit No.	Description	Reference
10.1	Escrow Agreement, dated as of May 9, 2007, by and among Modigene Inc., Abraham Havron, Shai Novik and Gottbetter & Partners, LLP	Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.2	Form of Registration Rights Agreement, dated as of May 9, 2007, by and between Modigene Inc. and the investors in the offering	Incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.3	Consulting Agreement between Modigene Inc. and Abraham (Avri) Havron	Incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.4	Amendment to Consulting Agreement between Modigene Inc. and Abraham (Avri) Havron	Incorporated by reference to Exhibit 10.4 to the Annual Report on Form 10-KSB filed with the SEC on March 31, 2008.
10.5	Amendment to Consulting Agreement between the Company and Abraham (Avri) Havron	Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on July 18, 2008.
10.6	Employment Agreement between Modigene Inc. and Shai Novik	Incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.7	First Amendment to Employment Agreement between Modigene Inc. and Shai Novik	Incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.8	Second Amendment to Employment Agreement between Modigene Inc. and Shai Novik	Incorporated by reference to Exhibit 10.7 to the Annual Report on Form 10-KSB filed with the SEC on March 31, 2008.
10.9	Amendment to Employment Agreement between the Company and Shai Novik	Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on July 18, 2008.
10.10	Employment Agreement between ModigeneTech and Eyal Fima	Incorporated by reference to Exhibit 10.9 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.11	Amendment to Employment Agreement between Modigene Inc. and Eyal Fima	Incorporated by reference to Exhibit 10.9 to the Annual Report on Form 10-KSB filed with the SEC on March 31, 2008.
10.12	Amendment to Employment Agreement between the ModigeneTech Ltd. and Eyal Fima	Incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the SEC on July 18, 2008.
10.13	Consulting Agreement between Modigene Inc. and Fuad Fares	Incorporated by reference to Exhibit 10.10 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.14	Amendment to Consulting Agreement between the ModigeneTech Ltd. and Fuad Fares	Incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on July 18, 2008.

Exhibit No.	Description	Reference
10.15	Modigene Inc. 2005 Stock Incentive Plan	Incorporated by reference to Exhibit 10.11 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.16	Modigene Inc. 2007 Equity Incentive Plan, as amended	Incorporated by reference to Exhibit 10.12 to the Annual Report on Form 10-KSB filed with the SEC on March 26, 2008.
10.17	Form of Stock Option Agreement under the 2005 Stock Incentive Plan	Incorporated by reference to Exhibit 10.13 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.18	Form of Stock Option Agreement under the 2007 Equity Incentive Plan	Incorporated by reference to Exhibit 10.14 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.19	Exclusive License Agreement dated February 2, 2007 between Modigene Inc. and Washington University	Incorporated by reference to Exhibit 10.15 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.20	Form of Clinical Advisory Panel Agreement	Incorporated by reference to Exhibit 10.16 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.21	Form of Scientific Advisory Board Agreement	Incorporated by reference to Exhibit 10.17 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
10.22	Agreement between Modigene Inc. and Cohen & Schaeffer P.C. and Steve Schaeffer	Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on March 6, 2008.
10.23	Securities Purchase Agreement among Modigene Inc., Frost Gamma Investments Trust, Jane Hsiao, Steven D. Rubin and Subbarao Uppaluri	Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on March 27, 2008.
10.24	Credit Agreement dated as of March 25, 2009 between Modigene Inc. and The Frost Group, LLC	Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on March 27, 2008.
10.25	Form of Note and Security Agreement between Modigene Inc. and The Frost Group, LLC	Incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on March 27, 2008.
10.26	Letter Agreement dated March 11, 2009, regarding Credit Agreement between Modigene Inc. and The Frost Group, LLC*	
21.1	Subsidiaries of Modigene Inc.	Incorporated by reference to Exhibit 21.1 to the Current Report on Form 8-K filed with the SEC on May 14, 2007.
23.1	Consent of BKR Yarel + Partners*	
31.1	CEO Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*	

Exhibit No.	Description	Reference
31.2	CFO Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*	
32	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*	

* Filed with the Annual Report on Form 10-K filed with the SEC on March 16, 2009.

SIGNATURES

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

Modigene Inc.

By: /s/ Abraham Havron

Abraham Havron
Chief Executive Officer

Date: March 16, 2009

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Abraham Havron</u> Abraham Havron	Chief Executive Officer (Principal Executive Officer) and Director	March 16, 2009
<u>/s/ Steve Schaeffer</u> Steve Schaeffer	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 16, 2009
<u>_____</u> Fuad Fares	Director	
<u>/s/ Phillip Frost</u> Phillip Frost	Director	March 16, 2009
<u>/s/ Marian Gorecki</u> Marian Gorecki	Director	March 16, 2009
<u>/s/ Jane Hsiao</u> Jane Hsiao	Director	March 16, 2009
<u>/s/ Shai Novik</u> Shai Novik	President and Director	March 16, 2009
<u>/s/ Steven Rubin</u> Steven Rubin	Director	March 16, 2009
<u>/s/ Adam Stern</u> Adam Stern	Director	March 16, 2009

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MODIGENE INC. AND SUBSIDIARY
(A development stage company)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2008 AND 2007
AND THE YEARS THEN ENDED

IN U.S. DOLLARS

MODIGENE INC. AND SUBSIDIARY
(A development stage company)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2008 AND 2007
AND THE YEARS THEN ENDED

IN U.S. DOLLARS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders of

MODIGENE INC. AND SUBSIDIARY (A Development Stage Company)

We have audited the accompanying consolidated balance sheets of Modigene Inc. (a development stage company) ("the Company") and its subsidiary as of December 31, 2008 and 2007, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2008 and 2007, and for the period from May 31, 2005 (inception date) through December 31, 2008. 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 consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by the management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company and its subsidiary as of December 31, 2008 and 2007, and the consolidated results of their operations, stockholders' equity and cash flows for the years ended December 31, 2008 and 2007, and for the period from May 31, 2005 (inception date) through December 31, 2008, in conformity with U.S. generally accepted accounting principles.

As described in Note 11 to the financial statements, the Company restated its financial statements for the year ended December 31, 2007 to reflect a correction of the accounting treatment of a reverse acquisition.

/s/ Yarel + Partners

Yarel + Partners
Certified Public Accountants

Tel-Aviv, Israel
March 16, 2009

MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED BALANCE SHEETS
U.S. dollars

	December 31,	
	2008	2007
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 7,465,232	\$ 11,455,807
Accounts receivable and prepaid expenses	412,515	506,144
Restricted cash	91,078	61,838
Total Current Assets	7,968,825	12,023,789
Property and Equipment, net	310,173	175,428
Long-term Assets:		
Severance pay fund	73,775	33,685
Long term deposit	1,894	2,951
Total Long Term Assets	75,669	36,636
Total Assets	\$ 8,354,667	\$ 12,235,853
 LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Short-term bank credit	\$	\$ 1,886
Trade payables	156,039	142,462
Related party payables	51,374	19,365
Accrued expenses and other liabilities	188,660	167,218
Total Current Liabilities	396,073	330,931
Accrued Severance Pay	90,732	42,552
Commitments and Contingent Liabilities		
Shareholders' Equity:		
Stock capital -		
Preferred stock of \$ 0.00001 par value –		
10,000,000 shares of preferred stock authorized		
800,000 shares issued and outstanding on December 31, 2008 and none on December 31, 2007	8	-
Common shares of \$ 0.00001 par value –		
300,000,000 shares of common stock authorized		
35,549,028 shares issued and outstanding on December 31, 2008 and 35,435,266 shares issued and outstanding on December 31, 2007	355	354
Additional paid-in capital (restated)	27,407,606	* 24,368,587
(Deficit) accumulated during the development stage (restated)	(19,540,107)	* (12,506,571)
Total Shareholders' Equity	7,867,862	11,862,370
Total Liabilities and Shareholders' Equity	\$ 8,354,667	\$ 12,235,853

* Restated, see note 11.

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

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

**CONSOLIDATED STATEMENTS OF OPERATIONS
U.S. dollars**

	Year ended December 31,		Period from May 31, 2005 (date of inception) to December 31, 2008
	2008	2007	2008
Revenues	\$ -	\$ -	\$ -
Operating expenses:			
In-process research and development write-off	-	*	(3,222,831)
Research and development, net	(4,781,089)	(1,998,735)	(7,545,435)
General and administrative	(2,410,015)	(1,668,060)	(9,317,574)
Operating (loss)	(7,191,104)	(3,666,795)	(20,085,840)
Financial income	438,349	365,338	841,687
Financial (expenses)	(280,781)	(11,746)	(295,954)
Net (loss)	\$ (7,033,536)	\$ * (3,313,203)	\$ (19,540,107)
(Loss) per share (basic & diluted)	\$ (0.20)	\$ (0.12)	\$ (0.83)
Weighted average number of shares outstanding	35,530,378	27,638,626	23,633,718

* Restated, see note 11.

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

MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)

STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE PERIOD MAY 31, 2005 (INCEPTION) TO DECEMBER 31, 2008

U.S. dollars

	Common stock		Additional	Deferred	(Deficit) accumulated	Total
	Shares	Amount	paid-in	compensation	during the	stockholders'
			capital		development	equity
					stage	
Balance as of May 31, 2005 (date of inception)	-	\$ -	\$ -	\$ -	\$ -	\$ -
Issuance of common stock	3,506,527	35	2,896,589	-	-	2,896,624
Issuance of common stock and options in conjunction with the acquisition of ModigeneTech Ltd.	3,788,632	38	2,628,528	-	-	2,628,566
Contributed capital	5,704,668	57	-	-	-	57
Stock based compensation	-	-	3,514,369	-	-	3,514,369
Deferred compensation on restricted shares to non-employees	588,725	6	362,591	(347,004)	-	15,593
Stock-based compensation related to options granted to non employees	-	-	76,885	-	-	76,885
Net (loss)	-	-	-	-	(6,977,419)	(6,977,419)
Balance as of December 31, 2005	13,588,552	136	9,478,962	(347,004)	(6,977,419)	2,154,675
Amortization of deferred compensation on restricted shares of common stock to non employees	-	-	-	347,004	-	347,004
Cumulative effect of first time adoption of the fair value based method for stock based compensation expenses to employees	-	-	3,415	-	-	3,415
Stock-based compensation on options	-	-	259,620	-	-	259,620
Net (loss)	-	-	-	-	(2,215,949)	(2,215,949)
Balance as of December 31, 2006	13,588,552	136	9,741,997	-	(9,193,368)	548,765

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

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

**STATEMENT OF STOCKHOLDERS' EQUITY (continued)
FOR THE PERIOD MAY 31, 2005 (INCEPTION) TO DECEMBER 31, 2008**

U.S. dollars

	Preferred stock		Common stock		Additional paid-in capital	Deferred compen- sation	(Deficit) accumulated during the development stage	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Issuance of common stock and options in conjunction with the reverse acquisition (restated)	-	-	7,333,339	73	* (73)	-	-	* -
Issuance of common stock and options in private placement	-	-	14,200,005	142	13,414,991	-	-	13,415,133
Options exercised	-	-	313,370	3	136	-	-	139
Stock-based compensation on options	-	-	-	-	1,211,536	-	-	1,211,536
Net (loss)	-	-	-	-	-	-	*(3,313,203)	(3,313,203)
Balance as of December 31, 2007	-	-	35,435,266	354	*24,368,587	-	*(12,506,571)	11,862,370
Issuance of preferred stock	800,000	8	-	-	1,999,992	-	-	2,000,000
Options exercised	-	-	113,762	(1)	-	-	-	-
Stock-based compensation on options	-	-	-	-	1,039,028	-	-	1,039,028
Net (loss)	-	-	-	-	-	-	(7,033,536)	(7,033,536)
Balance as of December 31, 2008	800,000	\$ 8	35,549,028	\$ 355	\$27,407,606	\$ -	\$(19,540,107)	\$ 7,867,862

* Restated, see note 11.

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

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars

	Year ended December 31,		Period from
	2008	2007	May 31, 2005 (date of inception) to December 31, 2008
<u>Cash flows from operating activities</u>			
Net (loss)	\$ (7,033,536)	*\$ (3,313,203)	\$ (19,540,107)
Adjustments to reconcile net (loss) to net cash (used in) operating activities:			
Depreciation	64,700	31,995	120,433
In-process research and development write-off	-	*	3,222,831
Stock based compensation	1,039,028	1,211,536	6,467,444
Increase in accrued severance pay, net	8,090	6,911	16,957
Decrease (increase) in accounts receivable and prepaid expenses	93,629	(468,369)	(412,238)
Increase in trade payables	13,577	86,435	145,935
Increase (decrease) in related party payables	32,009	(96,604)	51,374
Increase (decrease) in accrued expenses and other liabilities	21,442	(108,003)	67,644
Net cash (used in) operating activities	<u>(5,761,061)</u>	<u>(2,649,302)</u>	<u>(9,859,727)</u>
<u>Cash flows from investing activities</u>			
Purchase of property and equipment	(199,445)	(69,823)	(416,250)
Payment for the acquisition of ModigeneTech Ltd. (a)	-	-	(474,837)
Long term deposit	1,057	(1,211)	(1,894)
Restricted deposit	(29,240)	(9,767)	(91,078)
Net cash (used in) investing activities	<u>(227,628)</u>	<u>(80,801)</u>	<u>(984,059)</u>
<u>Cash flows from financing activities</u>			
Short term bank credit	(1,886)	(14,389)	(2,841)
Proceeds from loans	-	-	(173,000)
Principal payment of loans	-	-	173,000
Proceeds from issuance of shares	2,000,000	13,415,134	18,311,859
Net cash provided by financing activities	<u>1,998,114</u>	<u>13,400,745</u>	<u>18,309,018</u>
Increase (decrease) in cash and cash equivalents	<u>(3,990,575)</u>	<u>10,670,642</u>	<u>7,465,232</u>
Cash and cash equivalents at the beginning of the period	<u>11,455,807</u>	<u>785,165</u>	<u>-</u>
Cash and cash equivalents at the end of the period	<u>\$ 7,465,232</u>	<u>\$ 11,455,807</u>	<u>\$ 7,465,232</u>
Non cash transactions:			
Employee options exercised into shares	<u>\$ 1</u>	<u>\$ 139</u>	<u>\$ 140</u>
Issuance of common stock in reverse acquisition	<u>\$ -</u>	<u>\$ 73</u>	<u>\$ 73</u>
Additional information:			
Cash paid for income taxes	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>
Cash paid for interest expense	<u>\$ 280,796</u>	<u>\$ 11,746</u>	<u>\$ 295,969</u>

* Restated, see note 11.

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

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

U.S. dollars in thousands

	Year ended December 31,		Period from May 31, 2005 (date of inception) to December 31,
	2008	2007	2008
Issuance expenses	\$ -	\$ -	\$ (356,979)
Loan granted by the Company to ModigeneTech Ltd.	-	-	(497,575)
Cash at date of acquisition in ModigeneTech Ltd.	-	-	379,717
	\$ -	\$ -	\$ (474,837)

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

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2008 AND 2007**

U.S. dollars

NOTE 1:- GENERAL

a. General:

Modigene Inc. (the "Company") was formed on August 22, 2003 under the laws of the state of Nevada. The Company is engaged in the development of therapeutic proteins with extended half-lives, through its subsidiary, ModigeneTech Ltd. ("ModigeneTech").

The Company devotes substantially all of its efforts toward conducting research and development activities. In the course of such activities, the Company has sustained operating losses and expects such losses to continue for the foreseeable future. The Company has not generated any revenues or product sales and has not achieved profitable operations or positive cash flow from operations. The Company's deficit accumulated during the development stage aggregated \$19,540,107 through December 31, 2008. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis. During the year ended December 31, 2008, the Company raised \$2 million in a private placement, see note 7a below. Simultaneously with the \$2 million raised, the Company received from the same group of investors a line of credit pursuant to the Company may, at its discretion, borrow up to \$10,000,000, see note 6b below. The Company intends to use the line of credit during the third quarter of 2009. The Company is entitled to receive R&D grants from the Israeli government on approved projects during the year 2009, see note 6a. The Company believes that its current cash sources with the anticipated R&D grants will enable the continuance of the Company's activities for at least a year with no need of additional fundraising.

b. Recapitalization

On May 9, 2007, Modigene Inc., a Delaware corporation ("Modigene Delaware"), Modigene Acquisition Corp., a wholly-owned subsidiary of the Company (the "Acquisition Subsidiary") and the Company (Modigene Inc., formerly called LDG, Inc.), entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"). Pursuant to the Merger Agreement, the Acquisition Subsidiary merged (the "Merger") with and into Modigene Delaware, with Modigene Delaware remaining as the surviving entity and a wholly-owned subsidiary of the Company. The Company acquired the business of Modigene Delaware pursuant to the Merger and is continuing the existing business operations of Modigene Delaware as a publicly-traded company under the name Modigene Inc. In the Merger, the stockholders of Modigene Delaware received common stock of the Company in exchange for all their shares of common stock of Modigene Delaware. Pursuant to the Merger Agreement the Company became the holding company of Modigene Delaware and ModigeneTech.

Contemporaneously with the closing of the Merger and a private placement, as described below, the Company split off (the "Split-Off") its wholly-owned subsidiary, Liaison Design Group, LLC., through the sale of all of the membership interests of the subsidiary, upon the terms and conditions of a split-off agreement.

Effective May 9, 2007, the Company issued 13,588,552 shares of its common stock to the shareholders of Modigene Delaware, in exchange for all of the issued and outstanding common stock and Series A preferred stock of Modigene Delaware pursuant to the Merger Agreement.

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2008 AND 2007
U.S. dollars**

NOTE 1:- GENERAL (continued)

c. Acquisition of ModigeneTech Ltd.

In December 2005, Modigene Delaware acquired all of the outstanding shares of ModigeneTech in consideration for shares of common stock of Modigene Delaware. The fair value of the common stock issued and the options granted for the acquisition was \$2,628,566.

In conjunction with the transaction, Modigene Delaware also issued shares of common stock, valued at \$3,514,426, to the Company's founders for their services as the agents in the transaction (finders' fee).

Issuance expenses paid in cash in the amount of \$356,979 were also recorded as acquisition costs.

ModigeneTech was formed in April 2001 under the laws of Israel and ceased its operations during year 2004 due to lack of financing resources. The acquisition was accounted for as acquisition of group of assets that does not constitute a business and no goodwill was recognized.

The know-how purchased in the amount of \$3,222,831 has not yet reached technological feasibility and has no alternative future use other than the technological indications for which it was in development. Accordingly, the entire amount representing the know-how was recorded as in-process research and development and accordingly was immediately expensed in the consolidated statement of operations on the acquisition date. Following the acquisition of ModigeneTech, ModigeneTech became a wholly-owned subsidiary of Modigene Delaware. The financial statements of ModigeneTech were consolidated with the accounts of Modigene Delaware, commencing December 14, 2005.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The significant accounting policies followed in the preparation of the financial statements, on a consistent basis are:

a. Use of estimates:

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that 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 functional currency of the Company is the U.S. dollar, as the U.S. dollar is the primary currency of the economic environment in which the Company has operated and expects to continue to operate in the foreseeable future. The majority of ModigeneTech's operations are currently conducted in Israel. Most of the Israeli expenses are currently determined and paid in U.S. dollars. Financing and investing activities including loans and equity transactions are made in U.S. dollars.

Accordingly, monetary accounts maintained in currencies other than the dollar are remeasured into U.S. dollars in accordance with Statement No. 52 of the Financial Accounting Standards Board ("FASB"), "Foreign Currency Translation". All transaction gains and losses from the remeasurement of monetary balance sheet items are reflected in the statements of operations as financial income or expenses, as appropriate.

MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2008 AND 2007
U.S. dollars

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (continued)

c. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. Intercompany transactions and balances, have been eliminated upon consolidation.

d. Cash equivalents:

For purposes of reporting within the statement of cash flows, the Company considers all cash on hand, cash accounts not subject to withdrawal restrictions or penalties, and all highly liquid debt instruments purchased with a maturity of three months or less to be cash and cash equivalents.

e. Property and equipment:

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated by the straight-line method over the estimated useful lives of the assets. The annual depreciation rates are as follows:

	<u>%</u>
Office furniture and equipment	6
Laboratory equipment	15
Computers and electronic equipment	33
Leasehold improvements	25

The Company's long-lived assets are reviewed for impairment in accordance with Statement of Financial Accounting Standard No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144") whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. No impairments were recognized from May 31, 2005 (inception date) to December 31, 2008.

f. Accounting for stock-based compensation:

The Company's stock-based compensation are recorded according to Statement of Financial Accounting Standards No. 123 (revised 2004), "Stock-Based Payment" ("SFAS 123R"), which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and directors, including employee stock options under the Company's stock plans, based on estimated fair values. SFAS 123R requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's consolidated statement of operations. The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option-pricing model.

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2008 AND 2007
U.S. dollars**

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (continued)

g. Research and development costs and participations:

Research and development ("R&D") costs are expensed as they are incurred and consist of salaries, stock-based compensation benefits and other personnel related costs, fees paid to consultants, clinical trials and related clinical manufacturing costs, license and milestone fees, and facilities and overhead costs.

Participations from the Israeli government for development of approved projects are recognized as a reduction of expenses as the related costs are incurred (see note 6a and 9).

h. Severance pay:

The liability of ModigeneTech for severance pay is calculated pursuant to the Severance Pay Law in Israel, based on the most recent salary of the employees multiplied by the number of years of employment as of the balance sheet date and is presented on an undiscounted basis. ModigeneTech's employees are entitled to one month's salary for each year of employment or a portion thereof.

According to agreements with key employees who are related parties of the Company, upon retirement, the key employees will be entitled to receive a lump-sum payment, therefore the Company does not accumulate severance pay for those employees and the sum will be accrued when the Company has to pay such payments according to the employment agreements.

Severance expenses for the years ended December 31, 2008 and 2007 and the period from May 31, 2005 (inception date) through December 31, 2008 amounted to \$8,090, \$6,911 and \$16,957, respectively.

i. Income taxes:

The Company accounts for income taxes in accordance with Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" ("SFAS 109"). This statement prescribes the use of the liability method, whereby deferred tax assets and liability account balances 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.

j. Concentrations of credit risk:

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

Cash and cash equivalents are invested in major banks in Israel and in the U.S. Such deposits in the U.S. are not insured. Management believes that the financial institutions that hold the Company's investments are financially sound and, accordingly, minimal credit risk exists with respect to these investments.

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

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2008 AND 2007
U.S. dollars**

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (continued)

k. Fair value of financial instruments:

The following methods and assumptions were used by the Company in estimating its fair value disclosures for financial instruments: The carrying amounts of cash and cash equivalents, other receivables, trade payables and liabilities approximate their fair value due to the short-term maturity of such instruments.

l. Royalty-bearing grants:

Royalty-bearing grants from the Government of Israel for funding approved research and development projects are recognized at the time ModigeneTech is entitled to such grants, on the basis of the costs incurred and included as a deduction of research and development costs. Research and development grants received by ModigeneTech during the years ended December 31, 2008 and 2007 and the period from May 31, 2005 (inception date) through December 31, 2008 amounted to \$865,367, \$272,282, and \$1,237,517, respectively.

m. Loss per share:

Basic and diluted losses per share are presented in accordance with FASB issued SFAS no. 128 "Earnings per share" ("SFAS 128"). Outstanding share options and warrants have been excluded from the calculation of the diluted loss per share because all such securities are antidilutive. The total weighted average number of ordinary shares related to outstanding options and warrants excluded from the calculations of diluted loss per share were 7,620,546, 4,871,003 and 4,205,460 for the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008, respectively.

n. Revenue recognition:

Revenue, when generated, will be recognized in accordance with SEC Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements". The Company will recognize revenue when the significant risks and rewards of ownership have been transferred to the customer pursuant to applicable laws and regulations, including factors such as when there has been evidence of a sales arrangement, the performance has occurred, or service have been rendered, the price to the buyer is fixed or determinable, and collectibility is reasonably assured.

o. Restricted cash:

Cash and cash items which are restricted as to withdrawal or usage. Restricted cash includes legally restricted deposits held as compensating balances against a rent agreement to assure future credit availability.

p. Accounts receivable:

Accounts receivable are recorded at net realizable value consisting of the carrying amount less the allowance for uncollectible accounts. As of December 31, 2008 the Company has not accrued allowance for uncollectible accounts.

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2008 AND 2007**

U.S. dollars

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (continued)

q. Impact of recently issued accounting standards not yet adopted:

- In December 2007, the FASB issued SFAS No. 160 “Non-controlling Interests in Consolidated Financial Statements—an amendment of ARB No. 51.” SFAS 160 establishes accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. The guidance will become effective as of the beginning of our fiscal year beginning after December 15, 2008. The Company believes the adoption of this statement will not have a material impact on its consolidated financial statements.
- In December 2007, the FASB issued SFAS No. 141R “Business Combinations (revised 2007).” This statement replaces SFAS 141, Business Combinations. The statement provides guidance for how the acquirer recognizes and measures the identifiable assets acquired, liabilities assumed and any non-controlling interest in the acquiree. SFAS 141R provides for how the acquirer recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase. The statement determines what information to disclose to enable users to be able to evaluate the nature and financial effects of the business combination. SFAS 160 is effective for fiscal years beginning after December 15, 2008, and do not allow early adoption. The Company believes the adoption of this statement will not have a material impact on its consolidated financial statements.
- In September 2006, the Financial Accounting Standard Board (“FASB”) issued SFAS 157 “Fair Value Measures” (“SFAS 157”). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. In February 2008, the FASB issued FASB Staff Positions (“FSP”) 157-1, which amends SFAS 157 to remove leasing transactions accounted for under SFAS 13, “Accounting for Leases”, FSP 157-2, which deferred the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis to fiscal years beginning after November 15, 2008 and FSP 157-3, which clarifies the application of SFAS 157 in a market that is not active and illustrates considerations in determining the fair value of a financial asset when the market for the financial asset is not active. The Company is currently assessing the impact of SFAS No. 157 and FSP 157-2 and will adopt this standard at the beginning of the fiscal year ending on December 31, 2009. The Company believes the adoption of this statement will not have a material impact on its consolidated financial statements.
- In April 2008, the FASB issued FASB Staff Position (FSP) FSP 142-3, “Determination of the Useful Life of Intangible Assets.” This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, “Goodwill and Other Intangible Assets.” The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under Statement 142 and the period of expected cash flows to measure the fair value of the asset under FASB Statement No. 141 (Revised 2007), “Business Combinations,” and other U.S. generally accepted accounting principles (GAAP). This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company does not expect the adoption of FAS 142-3 to have a material effect on its results of operations and financial condition.

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2008 AND 2007
U.S. dollars**

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (continued)

q. Impact of recently issued accounting standards not yet adopted: (continued)

- In May 2008, the FASB issued FASB Staff Position (FSP) No. APB 14-1 "Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)." FSP APB 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer's non-convertible debt borrowing rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008, on a retroactive basis and will be adopted by the Company in the first quarter of fiscal 2009. The Company does not expect the adoption of FSP APB 14-1 to have a material effect on its results of operations and financial condition.

NOTE 3:- ACCOUNTS RECEIVABLE AND PREPAID EXPENSES

	December 31,	
	2008	2007
Government authorities	\$ 344,927	\$ 436,006
Prepaid expenses	34,989	70,000
Others	32,599	138
	\$ 412,515	\$ 506,144

NOTE 4:- PROPERTY AND EQUIPMENT, NET

	December 31,	
	2008	2007
Cost:		
Office furniture and equipment	\$ 20,479	\$ 4,141
Computers and electronic equipment	60,238	28,091
Laboratory equipment	306,855	201,587
Leasehold improvements	58,016	12,324
	445,588	246,143
Accumulated depreciation:		
Office furniture and equipment	2,045	1,237
Computers and electronic equipment	25,852	12,171
Laboratory equipment	89,122	51,492
Leasehold improvements	18,396	5,815
	135,415	70,715
Depreciated cost	\$ 310,173	\$ 175,428

Depreciation expenses for the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (inception date) through December 31, 2008 were \$64,700, \$31,995 and \$120,433, respectively.

**MODIGENE INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2008 AND 2007
U.S. dollars**

NOTE 5:- ACCRUED EXPENSES AND OTHER LIABILITIES

	December 31,	
	2008	2007
Employees and payroll accruals	\$ 95,689	\$ 62,008
Accrued expenses	92,971	95,528
Others		9,682
	\$ 188,660	\$ 167,218

NOTE 6:- COMMITMENTS AND CONTINGENT LIABILITIES

- a. ModigeneTech is committed to pay royalties to the Government of Israel with respect to the proceeds from sales of products which were developed in the framework of projects in which the Israeli Government participated in its expense. (see note 2g). Under the terms of the funding received from the Israeli Office of the Chief Scientist (the “Chief Scientist”), royalty payments are computed on the sales proceeds from such products at the rate of 3%. The contingent liability to the Chief Scientist is limited to the amount of the grants received plus interest at the rate of LIBOR. As of December 31, 2008, no royalties were accrued or paid. The Company is committed to the Chief Scientist to keep the know-how and production rights in the framework of the abovementioned projects under the ModigeneTech’s possession.
- b. On March 25, 2008, the Company entered into a Credit Agreement with a group of investors. Under this line of credit, the Company may, at its discretion, borrow up to \$10,000,000, which proceeds may be used for working capital or general corporate purposes of the Company, as approved by our board of directors (the “Board”). The maturity date for the line of credit is March 25, 2009, unless (i) the Company has borrowed any funds under the line of credit prior to March 25, 2009, or (ii) the Company elects to extend the line of credit. In either of such events the maturity date will be extended until March 25, 2013. Upon the maturity date, as the same may be extended, the Company is obligated to repay all outstanding borrowings, together with any accrued interest, and the line of credit will terminate. The Company is obligated to pay interest on outstanding borrowings under the line of credit at a 10% annual rate. In the event the Company determines to draw on the line of credit, or the Company elects to extend the maturity date until March 25, 2013, the Company will issue the Investors five-year warrants to purchase an aggregate of 1,500,000 shares of the Company’s non-registered Common stock, having an exercise price of \$0.99 per share. In March 2009, the lending shareholders agreed to grant the Company until April 30, 2009 to elect whether to extend the line of credit.
- c. The Company entered into a consulting agreement with its Chief Executive Officer (“CEO”), pursuant to which the CEO serves as Chief Executive Officer of the Company on a part-time basis, at an annual compensation rate of NIS 829,900 (according to the year end exchange rate, approximates \$218,280) and an annual cash bonus target of up to NIS 231,600 (according to the year end exchange rate, approximates \$60,000). The consulting agreement had an initial one-year term expiring December 14, 2006, with an option to extend by mutual agreement of the parties. The agreement was extended until December 14, 2009. Either

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NOTE 6:- COMMITMENTS AND CONTINGENT LIABILITIES (continued)

- c. party may terminate the agreement on 30 days prior notice, however, if the Company terminates the agreement for any reason other than the CEO's material breach, the CEO will be entitled to a lump sum severance payment of \$40,000.
- d. On January 1, 2007 the Company signed a 24-month consulting agreement with its Chief Scientific Officer ("CSO"), which can be extended for subsequent 12 months. Under the agreement, the Company will pay the CSO an annually consulting fee of NIS 138,960 (according to year end exchange rates, approximately \$36,549). In addition, the Company will pay milestone payments of up to \$102,000, upon successful completion of the milestones, as determined by the agreement. As of December 31, 2008 no milestone payments were paid or accrued. Upon the Company's termination of this agreement, the Company shall pay the CSO a lump sum of \$18,000.
- e. The Company entered into an employment agreement with its President. Such agreement provides for employment as President of the Company for an initial two-year term expiring December 14, 2007, which term shall be automatically extended for additional successive one-year terms on each one-year anniversary, unless either party gives written notice of an election not to renew the agreement. The agreement was automatically renewed on December 14, 2008. The President's annual base salary under the agreement is NIS 965,000 (according to year end exchange rates, approximately \$253,814). In addition, the President will be entitled to an annual cash bonus of up to NIS 328,100 (according to year end exchange rates, approximately \$85,000), based on corporate and personal milestones, along with equity performance awards, each as determined by the compensation committee of the Board. If the executive voluntarily terminates his employment (other than in connection with a change of control and certain other reasons), he will be entitled only to payment of his base salary through the date of termination, and will not be entitled to any performance bonus for that year. However, if the executive terminates the agreement as the result of a material breach by the Company, he will be entitled to payment of his base salary over a 12-month period following the termination, plus the value of any accrued benefits. If the Company terminates the employment other than for cause (as defined in the agreement), or if the term expires and is not renewed by the Company, the executive will be entitled to receive an amount equal to his then-current base salary over the 12-month period following termination, plus the value of accrued benefits and a pro-rata portion of the current year's performance bonus. If the executive is terminated for cause, he will be entitled to receive only any amounts that were due and owing to him at the time of such termination. If either (a) the executive terminates his employment for good reason (as defined in the agreement) or (b) the Company terminates the employment within 12 months of a change in control (as defined in the agreement), then the executive will be entitled to receive a lump-sum payment equal to the lesser of (i) his base salary for 12 months and (ii) his base salary for the remainder of the term, and all unvested stock options will immediately vest and be exercisable.

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NOTE 6:- COMMITMENTS AND CONTINGENT LIABILITIES (continued)

- f. The Company entered into an employment agreement with its Vice President of Product Development. The Vice President of Product Development's employment term is automatically extended for one-year term on December 14 of every year unless either party gives written notice, no less than 90 days prior to the end of the then-current term, of an election not to renew the agreement. The Vice President of Product Development's current annual base salary is NIS 386,000 (according to year end exchange rates, approximately \$101,526). In addition, he is entitled to an annual cash bonus of up to NIS 193,000 (according to year end exchange rates, approximately \$50,000), based on corporate and personal milestones, along with equity performance awards, each as determined by the Board.
- g. The Company renewed the Development and Manufacturing Service Agreement entered into on July 10, 2007. The total sum payable by the Company for the renewed agreement is \$2,050,000 of which as of December 31, 2008 approximately \$1,500,000 was paid by the Company.
- h. Operating leases:**

ModigeneTech rents its offices and motor vehicles under a lease operating agreement. Aggregate minimum rental commitments, under non-cancelable leases, as of December 31, 2008, are as follows:

<u>Year ended December 31,</u>	
2009	\$ 113,041
2010	16,364
2011	<u>3,472</u>
	<u>\$ 132,877</u>

Rent expenses for the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (date of inception) to December 31, 2008 were \$119,489, \$65,935 and \$267,593, respectively.

NOTE 7:- SHAREHOLDERS' EQUITY

- a. On March 25, 2008, the Company entered into a Securities Purchase Agreement with a group of related parties (the "Investors"), pursuant to which it sold to the Investors an aggregate of 800,000 shares of Series A preferred stock, \$0.00001 par value per share (the "Series A Preferred Stock"), at \$2.50 per share, for an aggregate purchase price of \$2,000,000. The Series A Preferred Stock is convertible during the period beginning March 1, 2009 through March 25, 2012, without payment of any additional consideration, into Common stock based on a conversion ratio equal to one share of Common stock per share of Series A Preferred Stock. In the event that the market capitalization of the Company equals or exceeds \$150,000,000 during any forty-five days within a consecutive ninety day period, the conversion ratio will adjust to five shares of Common stock per share of Series A Preferred Stock. The conversion ratio in effect will be proportionately adjusted for subdivisions, combinations, consolidations and similar corporate events. If not previously converted, the Series A Preferred Stock will automatically be converted into Common stock, at the applicable exchange ratio, on March 25, 2012.

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NOTE 7:- SHAREHOLDERS' EQUITY (continued)

- b. On May 9, 2007, simultaneously with the closing of the Merger discussed in note 1b., the Company completed the first phase of a private placement (the "Offering") of 6,418,814 units of its securities at a purchase price of \$1.50 per unit, with each unit consisting of one share of the Company's common stock and a five year warrant to purchase one-quarter of one share of the Company's common stock for an exercise price of \$2.50 per whole share.

The Company raised total cash consideration of \$9,628,212 before expenses. Upon the completion of the first phase of the Offering the Company issued warrants to purchase up to an aggregate of 242,324 shares of the Company's common stock to broker/dealers who assisted in the Offering.

Contemporaneously with the closing of the Merger and the first phase of the Offering, the Company completed a sale (the "Private Sale") of 5,377,660 shares of its common stock, and warrants to purchase 333,333 shares of common stock, to strategic investors, for total consideration of \$2,000,000.

The strategic investors were entitled to additional shares on a pro rata basis if additional units were sold in connection with the Offering. Pursuant to the terms of the Offering, the Company could sell additional units up to an aggregate of 8,666,672 units and \$13,000,008 (including those sold in the initial closing of the Offering). On May 21, 2007, the Company completed a second phase of the offering and closed on the sale of an additional 2,247,858 units, for total cash proceeds of \$3,371,766. Upon the completion of the second closing of the offering, the Company issued warrants to purchase up to an aggregate of 51,885 shares of common stock to the broker/dealers who assisted in the Offering and additional 155,673 shares of common stock (for no additional consideration) to the strategic investors. Issuance expenses paid in cash in the amount of \$1,584,878 were recorded as a reduction of additional paid in capital.

- c. **Rights of common stock capital:**

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of the stockholders, including the election of directors. Subject to any preferential rights of any outstanding series of preferred stock created by the Board from time to time, the common stockholders will be entitled to such cash dividends as may be declared from time to time by the Board from funds available. Subject to any preferential rights of any outstanding series of preferred stock, upon liquidation, dissolution or winding up of the Company, the common stockholders will be entitled to receive pro rata all assets available for distribution to such holders.

- d. **Rights of preferred stock:**

The Company has approved the designation of 800,000 shares of its preferred stock as "Series A Preferred Stock". Each holder of shares of Series A Preferred Stock shall be entitled, at the option of such holder, to convert all, but not less than all, of the shares of Series A Preferred Stock then held by such holder, at any time and from time to time beginning on March 1, 2009 and ending on March 25, 2012 (the "conversion deadline"), without the payment of any additional consideration, into common stock at the applicable

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NOTE 7:- SHAREHOLDERS' EQUITY (continued)

d. Rights of preferred stock: (continued)

conversion price discussed in note 1b. If any holder of shares of Series A Preferred Stock has not exercised his, her or its right to convert the shares of Series A Preferred Stock then held by such holder on or prior to the Conversion Deadline, then at the Conversion Deadline all such shares of Series A Preferred Stock will automatically convert, without the payment of any additional consideration, into common stock at the applicable conversion price discussed above. The holders of Series A Preferred Stock (and the holders of any other class or series of preferred stock that may have similar voting rights) will vote on an as-if-converted basis with the holders of common stock and any other class or series of preferred stock or common stock that by its terms, votes on an as-if-converted basis with the holders of common stock on all matters to be voted on by stockholders of the Company. Dividends will be payable only if, when and as declared by our Board of Directors, and, if declared, any such dividends will be non-cumulative. Such dividends, if any, will be paid out of, and to the extent of, any assets legally available therefor. No dividends will be declared or paid on the common stock, unless a dividend, payable in the same consideration or manner, is simultaneously declared or paid, as the case may be, on each share of Series A Preferred Stock. In the event of the liquidation of the Company, the entire remaining assets and funds of the Company legally available for distribution, if any, shall be distributed pro rata among the holders of the Series A Preferred Stock, the common stock and any other classes entitled to participate with common stock in proportion to the shares of common stock then held by them and the shares of common stock which they then have the right to acquire upon conversion of the capital stock held by them as of the date of such liquidation.

e. Warrants:

A summary of the warrants granted is as follows:

1.	Number of warrants	2,295,654
	Grant date	May 9, 2007
	Expiration date	May 8, 2012
	Exercise price	\$2.50
	Number of warrants vested	2,295,654
2.	Number of warrants	561,965
	Grant date	May 21, 2007
	Expiration date	May 20, 2012
	Exercise price	\$2.50
	Number of warrants vested	561,965

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NOTE 7:- SHAREHOLDERS' EQUITY (continued)

e. Warrants: (continued)

3.	Number of warrants	701,305
	Grant date	December 14, 2005
	Expiration date	December 13, 2015
	Exercise price	\$0.88
	Number of warrants vested	701,305

The warrants provide for the purchase of shares of common stock. The warrants, at the option of the holder, may be exercised by cash payment of the exercise price or by "cashless exercise." A "cashless exercise" means that in lieu of paying the aggregate purchase price for the shares being purchased upon exercise of the warrants in cash, the holder will forfeit a number of shares underlying the warrants with a "fair market value" equal to such aggregate exercise price. The Company will not receive additional proceeds to the extent that warrants are exercised by cashless exercise.

The exercise price and number of shares of common stock issuable on exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, or our recapitalization, reorganization, merger or consolidation.

f. Option plan:

- The Company issued stock options to purchase 5,132,623 shares of common stock, of which options to purchase 2,376,804 shares were granted under the Company's 2005 Stock Incentive Plan (the "2005 Plan" and options to purchase 2,755,819 shares were granted under the Company's 2007 Equity Incentive Plan (the "2007 Plan"). The Company accounts for stock based compensation using the fair value recognition provisions of SFAS No. 123R (revised 2004), "Share Based Payment".

The fair value of the stock options is estimated based upon grant date fair value using the Black-Scholes option-pricing model with the following weighted average assumptions used:

	Options granted under			
	2005 Plan		2007 Plan	
	Granted 2005	Granted 2006	Granted 2007	Granted 2008
annual dividends of	\$0.00	\$0.00	\$0.00	\$0.00
expected volatility of	85%	85%	85%	79%
risk-free interest rate of	4.41%	4.63%	4.67%	2.90%
expected average options expiration	8.05	7.9	9.19	9.94

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NOTE 7:- SHAREHOLDERS' EQUITY (continued)

f. Option plan: (continued)

2. A summary of the stock options granted under the 2005 and 2007 Plans is as follows:

	December 31, 2007	
	Number of Options	Weighted average Exercise Price
Outstanding at the beginning of the year	2,376,804	\$ 0.74
Forfeited	(245,639)	\$ 0.31
Exercised	(313,370)	\$0.0006
Granted	620,000	\$ 2.09
	2,437,795	\$ 1.26
Outstanding at the end of the year		
Options exercisable	1,867,795	\$ 1.01

	December 31, 2008	
	Number of Options	Weighted average Exercise Price
Outstanding at the beginning of the year	2,437,795	\$ 1.26
Forfeited	(27,560)	\$ 1.90
Exercised	(113,762)	\$ 0.00
Granted	2,135,819	\$ 0.96
	4,432,292	\$ 1.14
Outstanding at the end of the year		
Options exercisable	2,045,792	\$ 1.19

The options outstanding as of December 31, 2008, have been separated into exercise prices, as follows:

Exercise Price	Options Outstanding	Remaining Weighted average contractual life (years)	Options Exercisable
\$ 0.879	1,266,327	7.22	1,266,327
\$ 0.90	1,950,000	9.17	-
\$ 0.93	25,000	9.18	-
\$ 1.318	435,146	4.17	435,146
\$ 1.50	131,500	9.32	-
\$ 2.00	475,000	8.36	208,333
\$ 2.50	149,319	4.27	135,986
	4,432,292	7.87	2,045,792

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NOTE 7:- SHAREHOLDERS' EQUITY (continued)

f. Option plan: (continued)

Weighted average fair values and average exercise prices of options at date of grant and total aggregate intrinsic value of outstanding options are as follows:

	December 31,	
	2008	2007
Weighted average fair value on date of grant	\$0.72	\$1.06
Total aggregate intrinsic value	\$0.00	\$128,841.00

Stock based compensation expenses for the years ended December 31, 2008 and 2007 and for the period from May 31, 2005 (date of inception) through December 31, 2008 were \$1,039,028, \$1,211,536 and \$6,467,444, respectively. Stock based compensation for the period from May 31, 2005 (date of inception) through December 31, 2008 include stock based payments in the acquisition of a subsidiary as described in note 1c and deferred compensation on restricted shares in the amount of \$3,876,960.

NOTE 8:- INCOME TAXES

a. Losses for tax purposes:

The Company has adopted FASB Interpretation No. 48 ("Fin 48") "Accounting for Uncertainty in Income Taxes-an interpretation of FASB statement No. 109." Fin 48 requires companies to determine whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate authorities before any tax benefit can be recorded in the financial statements. It also provides guidance on recognition, measurement, classification, and disclosure in the financial statements for uncertain tax positions taken or expected to be taken in a tax return. The adoption of Fin 48 has had no effect on the Company's financial statements.

Carry-forward tax losses of the Company and ModigeneTech as of December 31, 2008 total approximately \$0 and \$10,712,000, respectively, which may be carried forward and offset against taxable income in the future for an indefinite period.

b. Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial purposes and the amounts used for income tax purposes.

As of December 31, 2008, the Company has provided full valuation allowances in respect of deferred tax assets. Management currently believes that since the Company has a history of losses it is more likely than not that the deferred tax regarding the loss carry-forward and other temporary differences will not be realized in the foreseeable future.

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NOTE 9:- RESEARCH AND DEVELOPMENT, NET

	Year ended December 31,		Period from May 31, 2005 (date of inception) to December 31,
	2008	2007	2008
Research and development expenses	\$ 5,527,102	\$ 2,667,733	\$ 9,060,314
Less – Government grants and participation	(746,013)	(668,998)	(1,514,879)
	<u>\$ 4,781,089</u>	<u>\$ 1,998,735</u>	<u>\$ 7,545,435</u>

As for the Company's government grants and participation – see note 6a.

NOTE 10:- SUBSEQUENT EVENTS

- a. On February 5, 2009 the Board approved the following:
- Issuance of stock options to its non-executive directors – 90,000 stock options with a 10 year contractual life, vested on the first anniversary, exercise price of \$0.65 per stock option.
 - Issuance of stock options to its executive directors and management – 250,000 stock options with a 10 year contractual life, vested in three equal annual installments, exercise price of \$0.65 per stock option.
 - Issuance of stock options to its employees – 35,500 stock options with a 10 year contractual life, vested in four equal annual installments, exercise price of \$0.65 per stock option.
- b. In March 2009, the lending shareholders as described in note 6b agreed to grant the Company until April 30, 2009 to elect whether to extend the line of credit.

NOTE 11:- AMENDED FINANCIAL STATEMENTS

On June 13, 2008, the Company received a comment letter from the United States Securities and Exchange Commission (“SEC”) regarding principally the accounting treatment of the May 2007 merger of Modigene Inc. into a wholly-owned subsidiary of the Company, as described in note 1b above. As part of the Company's response to the comment letter, an amendment to the Company's annual report on Form 10-KSB was filed to amend the accounting treatment of the merger to a recapitalization in the year 2007. In accordance with Statement of Financial Accounting Standards No. 141, the Company has restated the 2007 financial statements to record the merger as a reverse acquisition. The following financial statements line items were effected by the restatement:

	Originally reported	Restated	Difference
<u>Balance Sheets as of December 31, 2007:</u>			
Additional paid-in capital	\$ 35,368,596	\$ 24,368,587	\$ 11,000,009
(Deficit) accumulated during the development stage	\$ (23,506,580)	\$ (12,506,571)	\$ (11,000,009)

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NOTE 11:- AMENDED FINANCIAL STATEMENTS (continued)

Statements of Operations for the year ended December 31, 2007:

In-process research and development write-off	\$ (11,000,009)	\$ -	\$ (11,000,009)
Operating (loss)	\$ (14,666,804)	\$ (3,666,795)	\$ (11,000,009)
Net (loss)	\$ (14,313,212)	\$ (3,313,203)	\$ (11,000,009)
(Loss) per share (basic & diluted)	\$ (0.52)	\$ (0.12)	\$ (0.40)

Statement of Stockholders' Equity for the year ended December 31, 2007:

Additional paid-in capital	\$ 35,368,596	\$ 24,368,587	\$ 11,000,009
(Deficit) accumulated during the development stage	\$ (23,506,580)	\$ (12,506,571)	\$ (11,000,009)
Net (loss)	\$ (14,313,212)	\$ (3,313,203)	\$ (11,000,009)

Statement of Cash Flows for the year ended December 31, 2007:

Net (loss)	\$ (14,313,212)	\$ (3,313,203)	\$ (11,000,009)
In-process research and development write-off	\$ (11,000,009)	\$ -	\$ (11,000,009)