PLURISTEM THERAPEUTICS INC
Form 10-K
September 23, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended **June 30, 2009**

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from [ ] to [ ]

Commission file number **001-31392**

PLURISTEM THERAPEUTICS INC.

(Name of registrant as specified in its charter)

Nevada	**98-0351734**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
MATAM Advanced Technology Park, Building No. 20, Haifa, Israel	**31905**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number **011-972-74-7107171**

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

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.00001	**Nasdaq Capital Market**

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

None.

(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 o No x

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

Yes o No x

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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

o Yes o No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. x

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

Large accelerated filer o Accelerated filer o Non-accelerated filer o
Smaller reporting company x
(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 of the Act).
Yes o No x

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 last sold, or the average bid and asked prices of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter.

$4,528,717

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date.

15,796,181 as of September 10, 2009

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Our financial statements are stated in thousands United States Dollars (US$) and are prepared in accordance with United States Generally Accepted Accounting Principles (U.S. GAAP).

In this annual report, unless otherwise specified, all dollar amounts are expressed in United States dollars.

As used in this annual report, the terms we , us , our , the Company , and Pluristem mean Pluristem Therapeutics Inc. and our wholly owned subsidiary, unless otherwise indicated.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Annual Report on Form 10-K that are not historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Such forward-looking statements may be identified by, among other things, the use of forward-looking terminology such as believes, intends, plans expects, may, will, should, or anticipates negative thereof or other variations thereon or comparable terminology, and similar expressions are intended to identify forward-looking statements. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, or our achievements, or industry results, to be materially different from any future results, performance, levels of activity, or our achievements, or industry results, expressed or implied by such forward-looking statements. Such forward-looking statements appear in Item 1 Business and Item 7 Management s Discuss and Analysis of Financial Condition and Results of Operations, as well as elsewhere in this Annual Report and include statements regarding the following: the expected development and potential benefits from our products in treating various medical conditions, progress in our efforts to continue with clinical trials and achieve regulatory approvals, the potential market demand for our products, our expectations regarding our short- and long-term capital requirements, our outlook for the coming months and information with respect to any other plans and strategies for our business.

The factors discussed herein, including those risks described in Item 1A. Risk Factors , and expressed from time to time in our filings with the Securities and Exchange Commission could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this filing, and we undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

PART I

Item 1. Business.

Corporate History

We develop and intend to commercialize, cell therapy production technologies and products. We were incorporated in the State of Nevada under the name A.I. Software, Inc. on May 11, 2001. On June 10, 2003, we acquired from the Weizmann Institute of Science and the Technion-Israel Institute of Technology 100% of the issued and outstanding shares of a research and development company based in Israel called Pluristem, Ltd., which is now our wholly owned subsidiary.

On June 25, 2003, we changed our name from A.I. Software, Inc. to Pluristem Life Systems, Inc. From May 2003 until March 2006, our business was focused on the development of cell therapy production technologies for license to medical scientists and practitioners for their use in producing cell therapy products for sale. In March 2006, we changed our business model to focus on developing this technology in order to produce cell therapy products that we would sell ourselves. In July 2006, we achieved a breakthrough in our preclinical study of bone marrow transplantation: the preclinical study showed that by adding our PLX cells (PLacenta eXpanded cells) to umbilical cord blood (UCB) stem cells during bone marrow transplantation (BMT), hematopoietic stem cell engraftment in mice showed up to a 500% increase in engraftment after irradiation and chemotherapy. In January 2008,we achieved favorable results in demonstrating a revascularization effect after using our proprietary PLX-PAD cells for the treatment of limb ischemia associated with peripheral artery disease (PAD). In April 2008, an additional pre-clinical study utilizing our proprietary PLX cells in treating ischemic stroke showed statistical significance utilizing functional as well as anatomical endpoints.

On November 23, 2007, we changed our name to Pluristem Therapeutics Inc.

On December 10, 2007, our shares of common stock began trading on the NASDAQ Capital Market under the symbol PSTI. The shares were previously traded on the OTC Bulletin Board under the trading symbol PLRS.OB . On May 7, 2007, our shares also began trading on the Frankfurt Stock Exchange, under the symbol PJT.

In March 2009, the U.S. Food and Drug Administration cleared our Investigational New Drug application to initiate a Phase I clinical trial for the treatment of critical limb ischemia using our PLX-PAD product.

In June 2009, the Paul Ehrlich Institute (PEI), the German competent authority in the European Union, approved our clinical trial application (CTA) and granted approval for us to begin clinical trials with our proprietary placental-derived adherent stromal cell product, termed PLX-PAD.

In July 2009, the first patient was enrolled in a Phase I clinical trial of our PLX-PAD product at the Franziskus-Krankenhaus Hospital, Berlin.

In September 2009, we began enrolling patients in the U.S. for a Phase I clinical trial of our PLX-PAD product. The Phase I study is designed to evaluate the safety of PLX-PAD in patients with critical limb ischemia (CLI). On September 23, 2009 we announced the dosing of the first patient in the U.S. with our PLX-PAD product.

Our Current Business

Pluristem Therapeutics Inc. is a bio-therapeutics company dedicated to the commercialization of non-personalized (allogeneic) cell therapy products for the treatment of several severe degenerative, ischemic and autoimmune disorders. The Company is developing a pipeline of products, stored ready-to-use, that are derived from human placenta, a non-controversial, non-embryonic, adult stromal cell source.

These placental adherent stromal cells (ASCs) are grown in the Company s proprietary PluriX three-dimensional bioreactor, which imitates the natural microstructure of bone marrow and does not require supplemental growth factors or other exogenous materials.

Pluristem s first product in development, PLX-PAD, is intended to improve the quality of life of millions of people suffering from peripheral artery disease (PAD). The Company is in process of identifying its next clinical indication. The Company s main focus at this time is in the development of product candidates intended for local administration for indications such as: PAD, CLI, intermittent claudication, neuropathic pain, wound healing and orthopedic injuries. Additionally, the Company has reported favorable results administering PLX cells in systemically administration for indication such as: inflammatory bowel disease (IBD), multiple sclerosis, bone marrow transplantation (BMT) and ischemic stroke.

Once we have products ready for commercialization, we will evaluate our various sale and marketing alternatives, including licensing of our technology to other companies, manufacturing and direct sales or entering into marketing collaborations.

Scientific Background

Stem cells are unspecialized cells that can renew themselves for long periods through cell division and have the ability to differentiate into specialized cells. Stem cells are separated from other cells within the body by three general properties:

- they are capable of self-division and self-renewal over long time periods;
- they are unspecialized; and
- they can give rise to specialized cells.

Stem cells offer the possibility of renewable sources of replacement cells and new tissues to treat many kinds of diseases, conditions, and disabilities. All stem cells originate from three places: certain adult tissues (adult); UCB (umbilical); and the human embryo (embryonic). Stem cells obtained from a person after birth are adult stem cells and are found within various tissues that make up the body. These stem cells act as a repair and maintenance system, dividing regularly to provide the body with specialized cells to take the place of those that perish. Pluristem s technology employs only adult adherent stem cells from the placenta.

Our Technology

We are dedicated to the commercialization of non-personalized (allogeneic) cell therapy products. We are expanding non-controversial placental-derived adherent stromal cells (ASCs) via a proprietary 3D process, termed PluriX , into therapeutics for a variety of degenerative, malignant and autoimmune disorders.

The PluriX imitates the natural microstructure of bone marrow and does not require supplemental growth factors or other exogenous materials. Our PluriX Bioreactor System uses a three-dimensional system of stromal cell cultures and substrates to create an artificial physiological environment where placental stem cells (obtained after birth) can naturally grow and reproduce outside of the human body without any use of exogenous biologics or pharmacologicals. Using a natural growth mechanism eliminates the risk of genetic instability. Unlike conventional two-dimensional culturing methods, our three-dimensional microenvironment closely resembles the structure and function of the body s bone marrow environment. Our system aims to trick stem cells into growing and reproducing in the same way they would in living organs. Because the size and scale of the PluriX Bioreactor is larger than that of human bone marrow, stem cell growth can be greatly expanded. After the ASCs are grown in our PluriX reactor, the cells are then separated from the three-dimensional culture.

We believe that the resultant PLX (PLacental eXpanded) cell efficacy may be related to the secretion of cytokines or other potent immune modulators. Furthermore, PLX cells are immune privileged and have immunomodulatory properties, thus protecting the recipient from immunological reactions that often accompany transplantations.

Product Candidates

PLX-PAD

We are developing PLX-PAD cells as an allogeneic therapeutic product to treat CLI which results from PAD. Like all of our other stem cells, PLX-PAD cells are to be stored ready to use and shipped to hospitals and clinics for use as an intra-muscular treatment for the affected limb of a patient suffering from CLI. In 2008, we completed safety and bio-distribution studies in non-obese, diabetic, severe combined immunodeficient (NOD/SCID) mice. These studies indicated a statistically significant increase in new vessel formation (angiogenesis) and blood flow in an affected limb treated with PLX-PAD cells. In March 2009, the U.S. Food and Drug Administration cleared our Investigational New Drug application to initiate a Phase I clinical trial for the treatment of critical limb ischemia using our PLX-PAD product.

In June 2009, the Paul Ehrlich Institute (PEI), the German competent authority in the European Union, approved our clinical trial application (CTA) and granted approval for us to begin clinical trials of PLX-PAD.

In July 2009, the first patient was enrolled in a Phase I clinical trial of our PLX-PAD product at the Franziskus-Krankenhaus Hospital, Berlin.

In September 2009, we began enrolling patients in the U.S. for a Phase I clinical trial of our PLX-PAD product. The enrollment began at the Center for Therapeutic Angiogenesis in Birmingham, Alabama. In addition, Duke University Medical Center will be screening patients for the trial. The Phase I study is designed to evaluate the safety of PLX-PAD in patients with CLI. A total of up to 12 adults with the disease will be included in this dose escalating trial. On September 23, 2009 we announced the dosing of the first patient in the U.S. with our PLX-PAD product.

Critical Limb Ischemia

Peripheral artery occlusive disease (PAOD), also known as peripheral vascular disease (PVD) or, more commonly, PAD is a term used to describe diseases caused by the obstruction of peripheral arteries resulting from atherosclerosis or other inflammatory processes that can lead to ischemia. CLI is the severe subset and natural endpoint of PAD.

PAD and CLI are aggravated by conditions such as hypercholesterolemia, smoking and diabetes with the incidence doubling in patients with these risk factors. One system for staging peripheral artery disease severity is the Rutherford categories 1 through 6, with critical limb ischemia defined by category 4 (ischemic rest pain), category 5 (minor tissue loss), and category 6 (ulceration or gangrene). The severity of the manifestations is often a reflection of the degree of obstruction in the arterial perfusion of the extremity. Analysis of data from the 2009 update on heart disease and stroke statistics published in the journal *Circulation* (*Circulation.* 2009;119:e21-e181. Published online before print December 15, 2008) indicates that approximately 8 million people over the age of 40 in the United States are with afflicted with PAD. PAD increases significantly with age, rising to as high as approximately 20% of the population of those over the age of 70, which has resulted in a growing market for therapies intended to treat this disorder. It has been estimated that CLI affects approximately 1.1 million U.S. patients and is anticipated to grow to approximately 1.4 million patients by 2015 according to The Sage Group Report of September 12, 2005. This could result in approximately 160,000 to 200,000 PAD-amputations performed annually in the United States.

Additionally we have reported favorable results administering PLX cells in systemically administration in several indications, the table below summaries the status of these studies:

Product	For the treatment of	Status
PLX-IBD	Inflammatory bowel disease	Pre- Clinical
PLX-STROKE	Ischemic stroke	Pre- Clinical
PLX-BMT	Bone marrow transplantation	Pre- Clinical
PLX-MS	Multiple sclerosis	Proof of concept

Intellectual Property

Our success will depend in part on our ability to protect our technology and products with patents. Our technology is patented in the U.S., Australia, Russia, Mexico, China, Hong Kong, India, New Zealand and South Africa. The earliest of these patents will expire in 2020. In addition, we have patents pending in Europe, Canada, Japan and other countries.

The patents included in our portfolio address the composition, processes and therapeutic use of adherent stromal cells. We are committed to protecting our intellectual property position and to aggressively pursue our patent portfolio.

Through our experience with ASC-based product development, we have developed expertise and know-how in this field. We are in the final stage of building our ability to manufacture clinical grade ASCs in-house. To protect this non-patentable know-how, our policies require confidentiality agreements with our employees, consultants, contractors, manufacturers and advisors. These agreements generally provide for protection of confidential information, restrictions on the use of materials and assignment of inventions conceived during the course of performance for us. These agreements might not effectively prevent disclosure of our confidential information.

We fully own our intellectual property and we have no obligations to pay royalties to any third party, except for royalties to the OCS (see note 7D in our audited consolidated financial statements for fiscal 2009 included elsewhere in this Form 10-K).

Research and Development

We spent on research and development $3,141,000 and $4,393,000 on fiscal year 2009 and 2008, respectively.

Foundational Research. Our core technology, the PluriX Bioreactor system, was developed by our former Chief Technology Officer, Dr. Shai Meretzki of the Technion - Israel Institute of Technology s Rappaport Faculty of Medicine. Dr. Meretzki also worked in close collaboration with Professor Dov Zipori and Dr. Avinoam Kadouri of the Weizmann Institute of Science. Professor Zipori specializes in cultures and stromal cells and Dr. Kadouri specializes in the planning and creation of bioreactors.

Ongoing Research and Development Plan.

In July 2007, we entered into a five years collaborative research agreement with the Center for Regenerative Therapies at Charite University Hospital of Berlin (BCRT). Pluristem and BCRT are collaborating on a variety of indications utilizing adherent stromal cells derived from the placenta that have been expanded in the Company s proprietary bioreactor. The initial successful project collaboration was for developing and characterizing the mechanism of action of the PLX-PAD cells in allogeneic therapeutic product to treat CLI, which results from peripheral artery disease PAD. According to the agreement, we will be the exclusive owner of the technology and any products produced as a result of the collaboration. In December 2008 we have entered into a clinical trials agreement with the BCRT, and accordingly the BCRT will be one of our clinical sites in Germany for the CLI clinical trials.

Our research and development facilities are in Haifa, Israel. The facility has been approved as a Good Manufacturing Practices (GMP) standard site for the purpose of manufacturing PLX cells by an inspector from the European Medicines Agency (EMEA). In addition, the U.S. Food and Drug Administration (FDA) approved the design of the clean room. The research and development facilities include 13,800 square feet in total.

We receive the placentas used for our research activities from hospitals in Israel. Any medical waste related to the use of placentas is treated in compliance with environmental laws and standards.

Government Regulation

The development, manufacture, commercialization and reimbursement of our cell therapy product candidates are subject to the laws and regulations of governmental authorities in the U.S. and other countries in which our products will be marketed in the future. Specifically, in the U.S., the FDA, among other activities, regulates new product approvals to establish safety and efficacy of these products, furthermore, various governmental statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage and record keeping related to such products and their marketing. Governments in other countries have similar requirements for testing and marketing.

Regulatory Process in the United States

Our product candidates are subject to regulation as biological products under the Public Health Service Act and the Food, Drug and Cosmetic Act. The FDA generally requires the following steps for pre-market approval or licensure of a new biological product:

- Preclinical laboratory and animal tests conducted in compliance with the FDA s Good Laboratory Practice, or GLP, requirements to assess a drug s biological activity and to identify potential safety problems, and to characterize and document the product s chemistry, manufacturing controls, formulation, and stability. We conduct preclinical testing for internal use and as support for submissions to the FDA. Preclinical testing generally included various types of in-vitro laboratory evaluations of the PLX-PAD product candidate as well as animal studies to assess the safety and the functionality of the product,

- Submission to the FDA of an Investigational New Drug, or IND application, which must become effective before clinical testing in humans can begin; following submission of the IND, the FDA has 30 days to review the application and raise safety and other clinical trial issues. If we are not notified of objections within that period, clinical trials may be initiated, and human clinical trials may commence at a specified number of investigational sites with the number of patients approved by the FDA. We have submitted one IND for our PLX-PAD product candidate, and we are conducting a clinical study under this IND.

- Obtaining approval of Institutional Review Boards, or IRBs, of research institutions or other clinical sites to introduce the biologic drug candidate into humans in clinical trials; adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication conducted in compliance with the FDA s Good Clinical Practice, or GCP, requirements. We have obtained approval from two IRBs: (i) Western Institutional Review Board or WIRB, on behalf of the Center for Therapeutic Angiogenesis in Birmingham, Alabama, (ii) The Duke University Health System Institutional Review Board or DUHS IRB, on behalf of Duke University Medical Center. Our phase I study utilizing our PLX-PAD product candidate for the treatment of Critical Limb Ischemia patients,

- Compliance with current Good Manufacturing Practices, or cGMP regulations and standards;

- Submission to the FDA of a Biologics License Application, or BLA, for marketing that includes adequate results of preclinical testing and clinical trials;

FDA reviews the marketing application in order to determine, among other things, whether the product is safe, effective and potent for its intended uses; and obtaining FDA approval of the BLA, including inspection and approval of the product manufacturing facility as compliant with cGMP requirements, prior to any commercial sale or shipment of the pharmaceutical agent.

The FDA may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals.

Regulatory Process in Europe

The European Union (EU) has approved a regulation specific to cell and tissue products and our PLX-PAD cell therapy product candidate is regulated under this Advanced Therapy Medicinal Product (ATMP) regulation, or the EU Directive.

For products that are regulated as an ATMP, the EU Directive requires:

(i) Preclinical laboratory and animal testing;

(ii) Filing a Clinical Trial Application (CTA) with an Investigational Medicinal Product Dossier (IMPD) with the Competent Authority of each EU Member State (MS) in which it intends to conduct human clinical trials. The MS Competent Authority has 90 days to review the application and raise safety and other clinical trial issues. The EU Clinical Directive allows the Competent Authority to extend this review period if it deems it necessary for the safety of the patient or if it needs additional time to conduct a thorough review.

(iii) Obtaining approval of Ethic Committees of research institutions or other clinical sites to introduce the biologic drug candidate into humans in clinical trials; adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication conducted in compliance with the Good Clinical Practice requirements.

(iv) Adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use;

(v) Submission to EMEA for a Marketing Authorization (MA); and,

(vi) Review and approval of the MA.

We have submitted and obtained approval for one CTA for our PLX-PAD product in Germany, and we have obtained approval from the local Ethic Committee of Berlin and are conducting a clinical study under this approval for our phase I study utilizing the PLX-PAD product for the treatment of Critical Limb Ischemia patients.

Employees

We presently employ a total of 34 full-time employees and 3 part-time employees, of whom 28 full-time employees and 2 part-time employees are engaged in research.

Competition

The cellular therapeutics industry, of which we are a part, is subject to technological changes that can be rapid and intense. We have faced, and will continue to face, intense competition from biotechnology, pharmaceutical and biopharmaceutical companies, academic and research institutions and governmental agencies engaged in cellular therapeutic and drug discovery activities or funding, both in the United States and internationally. Some of these competitors are pursuing the development of cellular therapeutics, drugs and other therapies that target the same diseases and conditions that we target in our clinical and pre-clinical programs.

We are aware of many companies working in this area, including: Osiris Therapeutics, Aastrom Biosciences, Cytori Therapeutics, Gamida Cell, Geron, Mesoblast and Celgene. We expect to compete based upon, among other things, our intellectual property portfolio, our manufacturing efficiencies and the efficacy of our products. Our ability to compete successfully will depend on our continued ability to attract and retain experienced and skilled executive, scientific and clinical development personnel to identify and develop viable cellular therapeutic candidates and exploit these products commercially.

Item 1A. Risk Factors.

The following risk factors, among others, could affect our actual results of operations and could cause our actual results to differ materially from those expressed in forward-looking statements made by us. These forward-looking statements are based on current expectations and we assume no obligation to update this information. You should carefully consider the risks described below and elsewhere in this annual report before making an investment decision. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. Our common stock is considered speculative and the trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. The following risk factors are not the only risk factors facing our company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business.

We have not earned any revenues since our incorporation and only have a limited operating history in our current business of developing and commercializing stem cell production technology, which raise doubts about our ability to continue as a going concern.

We have a limited operating history in our current business of developing and commercializing stem cell production technology and must be considered in the development stage. We have not generated any revenues since our inception and we will, in all likelihood, continue to incur operating expenses without significant revenues until we successfully develop our stem cell production technology and commercialize our cell therapy products. Our primary source of funds has been the sale of our common stock. We cannot give assurances that we will be able to generate any significant revenues or income. These circumstances make us dependent on additional financial support until profitability is achieved. There is no assurance that we will ever be profitable or that we will be able to continue as a going concern as is noted in the notes to our consolidated financial statements for the year ended June 30, 2009.

Our independent registered public accounting firm s report states that there is a substantial doubt that we will be able to continue as a going concern.

Our independent registered public accounting firm, Kost, Forer, Gabbay & Kassierer a Member of Ernst & Young Global, state in their audit report attached to our audited consolidated financial statements for the fiscal years that ended June 30, 2009 and 2008 that since we are an exploration stage company, we have no established source of revenue, and are dependent on our ability to raise capital from shareholders and other sources to sustain operations, there is a substantial doubt that we will be able to continue as a going concern. There can be no assurance that acceptable financing to fund our ongoing operations can be obtained on suitable terms, if at all. If we are unable to obtain the financing necessary to support our operations, we may be unable to continue as a going concern. In that event, we may be forced to cease operations and our stockholders could lose their entire investment in our company.

Our likelihood of profitability depends on our ability to develop and commercialize products based on our stem cell production technology, which is currently in the development stage. If we are unable to complete the development and commercialization of our stem cell products successfully, our likelihood of profitability will be limited severely.

We are engaged in the business of developing cell therapy products. We have not realized a profit from our operations to date and there is little likelihood that we will realize any profits in the short or medium term. Any profitability in the future from our Company s business will be dependent upon successful commercialization of our potential cell therapy products, which will require significant additional research and development as well as substantial clinical trials.

If we are not able to successfully develop and commercialize our cell therapy product candidates and obtain the necessary regulatory approvals, we may not generate sufficient revenues to continue our business operations.

Our early stage cell therapy product candidates may fail to perform as we expect. Moreover even if our cell therapy product candidates will successfully perform as expected, in later stages of development may fail to show the desired safety and efficacy traits despite having progressed successfully through preclinical or initial clinical testing. We will need to devote significant additional research and development, financial resources and personnel to develop commercially viable products and obtain the necessary regulatory approvals.

If our cell therapy product candidates do not prove to be safe and efficacious in clinical trials, we will not obtain the required regulatory approvals. If we fail to obtain such approvals, we may not generate sufficient revenues to continue our business operations.

Even if we obtain regulatory approval of a product, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers and manufacturing facilities, which may create additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer or facility, may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, regulatory agencies may establish additional regulations that could prevent or delay regulatory approval of our products.

We cannot market and sell our cell therapy product candidates in the United States or in other countries if we fail to obtain the necessary regulatory approvals or licensure.

We cannot sell our cell therapy product candidates until regulatory agencies grant marketing approval, or licensure. The process of obtaining regulatory approval is lengthy, expensive and uncertain. It is likely to take several years to obtain the required regulatory approvals for our cell therapy product candidates, or we may never gain the necessary approvals. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our operations and cause our stock price to decline significantly.

To obtain marketing approvals in the United States for cell therapy product candidates we must, among other requirements, complete carefully controlled and well-designed clinical trials sufficient to demonstrate to the FDA that the cell therapy product candidates is safe and effective for each disease for which we seek approval. So far, we are at the beginning of conducting Phase I clinical trials for our PLX-PAD product, which is our only product that is the subject to clinical trials. Several factors could prevent completion or cause significant delay of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that cell therapy product candidates are safe, effective and potent for use in humans. Negative or inconclusive results from or adverse medical events during a clinical trial could cause the clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful. The FDA can place a clinical trial on hold if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury. If safety concerns develop, we or the FDA could stop our trials before completion.

If we encounter problems or delays in the research and development of our potential cell therapy products, we may not be able to raise sufficient capital to finance our operation during the period required to resolve such problems or delays.

Our cell therapy products are currently in the development stage and we anticipate that we will continue to incur operating expenses without significant revenues until we have successfully completed all necessary research and clinical trials. We, and any of our potential collaborators, may encounter problems and delays relating to research and development, regulatory approval and intellectual property rights of our technology. Our research and development programs may not be successful, and our cell culture technology may not facilitate the production of cells outside the human body with the expected result. Our cell therapy products may not prove to be safe and efficacious in clinical trials. If any of these events occur, we may not have adequate resources to continue operations for the period required to resolve the issue delaying commercialization and we may not be able to raise capital to finance our continued operation during the period required for resolution of that issue. Accordingly, we may be forced to discontinue or suspend our operations.

If we are not able to conduct our clinical trials properly and on schedule, marketing approval by FDA and other regulatory authorities may be delayed or denied.

The completion of our clinical trials may be delayed or terminated for many reasons, including, but not limited to, if:

- the FDA does not grant permission to proceed and places the trial on clinical hold;
- subjects do not enroll in our trials at the rate we expect;
- subjects experience an unacceptable rate or severity of adverse side effects;
- third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice and regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by the FDA or Institutional Review Boards (IRBs) of research institutions participating in our clinical trials find regulatory violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit us from using some or all of the data in support of our marketing applications; or
- one or more IRBs suspends or terminates the trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial.

Our development costs will increase if we have material delays in our clinical trials, or if we are required to modify, suspend, terminate or repeat a clinical trial. If we are unable to conduct our clinical trials properly and on schedule, marketing approval may be delayed or denied by the FDA.

We may not be able to secure and maintain research institutions to conduct our clinical trials.

We rely on research institutions to conduct our clinical trials. Specifically, the limited number of centers experienced with cell therapy products candidates heightens our dependence on such research institutions. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreement with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. We may not be able to secure and maintain suitable research institutions to conduct our clinical trials.

We need to raise additional financing to support the research and development of our cell therapy products and our products in the future but we cannot be sure we will be able to obtain additional financing on terms favourable to us when needed. If we are unable to obtain additional financing to meet our needs, our operations may be adversely affected or terminated.

Our ability to continue to develop and commercialize our potential cell therapy products is dependent upon our ability to raise significant additional financing when needed. If we are unable to obtain such financing, we will not be able to fully develop our technology and commercialize our cell therapy products. Our future capital requirements will depend upon many factors, including:

- continued scientific progress in our research and development programs;
- costs and timing of conducting clinical trials and seeking regulatory approvals and patent prosecutions;
- competing technological and market developments;
- our ability to establish additional collaborative relationships; and
- the effect of commercialization activities and facility expansions if and as required.

We have limited financial resources and, to date, negative cash flow from operations. Although we anticipate that our existing capital resources will be adequate to satisfy our working capital and capital expenditure requirements until at least March 2010, we will need to raise additional funds in the near future in order to satisfy our working capital and capital expenditure requirements. Therefore, we are dependent on our ability to sell our common stock for funds, receive grants or to otherwise raise capital. There can be no assurance that we will be able to obtain financing on that basis in light of the market demand for our securities, the state of financial markets generally, and other relevant factors. Any sale of our common stock in the future will result in dilution to existing stockholders. Furthermore, there is no assurance that we will not incur debt in the future, that we will have sufficient funds to repay our future indebtedness, or that we will not default on our future debts, jeopardizing our business viability. Finally, we may not be able to borrow or raise additional capital in the future to meet our needs or to otherwise provide the capital necessary to conduct the development and commercialization of our potential cell therapy products, which could result in the loss of some or all of one s investment in our common stock.

We cannot guarantee continuation of government programs and tax benefits.

We have in the past received certain Israeli government approval under certain programs and may in the future utilize certain tax benefits in Israel by virtue of these programs. To remain eligible for such tax benefits, we must continue to meet certain conditions, including making some specified investments in fixed assets. If we fail to comply with these conditions in the future, the benefits we receive could be canceled and we may pay certain taxes. We cannot guarantee that these programs and tax benefits will be continued in the future, at their current levels or at all. If these programs and tax benefits are ended, our business, financial condition and results of operations could be negatively affected.

Because we received grants from the Israeli Office of the Chief Scientist, we are subject to ongoing restrictions.

We received royalty-bearing grants from the Israeli Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or the Chief Scientist, for research and development programs that meet specified criteria. The terms of the Chief Scientist s grants limit our ability to transfer know-how developed under an approved research and development program outside of Israel, regardless of whether the royalties were fully paid. Any non-Israeli citizen, resident or entity that, among other things, becomes a holder of 5% or more of our share capital or voting rights, is entitled to appoint one or more of our directors or our chief executive officer, serves as a director of our company or as our chief executive officer is generally required to notify the same to the Chief Scientist and to undertake to observe the law governing the grant programs of the Chief Scientist, the principal restrictions of which are the transferability limits described above.

We are exposed to fluctuations in currency exchange rates.

A significant portion of our business is conducted outside the United States. Therefore, we are exposed to currency exchange fluctuations in other currencies such as the Euro and the New Israeli Shekel (NIS). Moreover, a portion of our expenses in Israel and Europe are paid in NIS and Euros, respectively, which subjects us to the risks of foreign currency fluctuations. Our primary expenses paid in NIS are employee salaries, fees for consultants and subcontractors and lease payments on our Israeli facilities.

The dollar cost of our operations in Israel will increase to the extent increases in the rate of inflation in Israel are not offset by a devaluation of the NIS in relation to the dollar, which would harm our results of operations.

Since a considerable portion of our expenses such as employees salaries are linked to an extent to the rate of inflation in Israel, the dollar cost of our operations is influenced by the extent to which any increase in the rate of inflation in Israel is or is not offset by the devaluation of the NIS in relation to the dollar. As a result, we are exposed to the risk that the NIS, after adjustment for inflation in Israel, will appreciate in relation to the dollar. In that event, the dollar cost of our operations in Israel will increase and our dollar-measured results of operations will be adversely affected. During the past few years inflation-adjusted NIS appreciated against the dollar, which raised the dollar cost of our Israeli operations. We cannot predict whether the NIS will appreciate against the dollar or vice versa in the future. Any increase in the rate of inflation in Israel, unless the increase is offset on a timely basis by a devaluation of the NIS in relation to the dollar, will increase labor and other costs, which will increase the dollar cost of our operations in Israel and harm our results of operations.

If we fail to obtain and maintain required regulatory approvals for our potential cell therapy products, our ability to commercialize our potential cell therapy products will be limited severely.

Once our potential cell therapy products are fully developed, we intend to market our potential cell therapy products primarily in the United States and Europe. We must obtain FDA approval of our technology and potential cell therapy products before commercialization of our potential cell therapy products may commence in the United States and similar agencies in Europe. We may also be required to obtain additional approvals from foreign regulatory authorities to commence our marketing activities in those jurisdictions. If we cannot demonstrate the safety, reliability and efficacy of our cells, including long-term sustained cell engraftment, or if one or more patients die or suffer severe complications in clinical trials, the FDA and/or other regulatory authorities could delay or withhold regulatory approval of our technology and potential products.

Furthermore, even if we obtain regulatory approval for our cell therapy products, that approval may be subject to limitations on the indicated uses for which they may be marketed. Even after granting regulatory approval, the FDA, other regulatory agencies, and governments in other countries will continue to review and inspect marketed products, manufacturers and manufacturing facilities. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market. Further, governmental regulatory agencies may establish additional regulations, which could prevent or delay regulatory approval of our technology and our potential cell therapy products.

We have very limited experience in conducting and managing human trials. If we fail in the conducting of such trials, our business will be materially harmed.

Even though we have recruited in the past year employees who are experienced in managing and conducting clinical trials, we still have very limited experience in this area. We will need to expand on our experience in order to obtain regulatory approvals for our therapeutic product candidates. The failure to successfully conduct clinical trials could materially harm our business.

The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies having greater financial resources and discovery technological capabilities, thus intensifying competition in these industries. This trend may also result in fewer potential collaborators or licensees for our therapeutic product candidates. Also, if a consolidating company is already doing business with our competitors, we may lose existing licensees or collaborators as a result of such consolidation.

This trend may adversely affect our ability to enter into agreements for the development and commercialization of our product candidates, and as a result may harm our business.

Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our therapeutics creates significant challenges in regards to product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, the FDA has relatively limited experience with stem cell therapies. None has been approved by the FDA for commercial sale, and the pathway to regulatory approval for our cell therapy product candidates may accordingly be more complex and lengthy. As a result, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

There are no FDA approved treatments for some of the disease indications we are pursuing. This could complicate and delay FDA approval of our biologic drug candidates.

There are no drugs or therapies currently approved with for treatment of PAD using allogeneic cell therapy products. As a result, the clinical efficacy endpoints, or the criteria to measure the intended results of treatment may be difficult to determine. In addition, patients battling PAD and who, therefore, are candidates for treatment with PLX-PAD, are typically suffer from complications and disorders that may bring to amputation and other complications prior to the completion of the study. This resulting reduction in the number of patients available for evaluation at the end of the study may make it more difficult for us to demonstrate efficacy, as necessary to obtain FDA approval to market our products.

Our cell therapy drug candidates represent new classes of therapy that the marketplace may not understand or accept.

Even if we successfully develop and obtain regulatory approval for our biologic drug candidates, the market may not understand or accept them. We are developing cell therapy product candidates that represent novel treatments and will compete with a number of more conventional products and therapies manufactured and marketed by others, including major pharmaceutical companies. The degree of market acceptance of any of our developed and potential products will depend on a number of factors, including:

- the clinical safety and effectiveness of our cell therapy drug candidates and their perceived advantage over alternative treatment methods;
- adverse events involving our cell therapy product candidates or the products or product candidates of others that are stem cell based; and
- the cost of our products and the reimbursement policies of government and third-party payors.

If the health care community does not accept our potential products for any of the foregoing reasons, or for any other reason, it could affect our sales, having a material adverse effect on our business, financial condition and results of operations.

We are dependent upon third-party suppliers for raw materials needed for the manufacture; if any of these third parties fail or are unable to perform in a timely manner, our ability to manufacture and deliver will be compromised.

In order to produce our call therapy product candidates, we require certain raw of materials in addition to the placenta used in our manufacturing process. These items must be manufactured and supplied to us in sufficient quantities and in compliance with GMP. To meet these requirements, we have entered into supply agreements with firms that manufacture these components to GMP standards. Our requirements for these items are expected to increase if and when we transition to the manufacture of commercial quantities of our biologic drug candidates.

In addition, as we proceed with our clinical trial efforts, we must be able to continuously demonstrate to the FDA and the EMEA, that we can manufacture our cell therapy product candidates with consistent characteristics. Accordingly, we are materially dependent on these suppliers for supply of GMP-grade components of consistent quality. Our ability to complete ongoing clinical trials may be negatively affected in the event that we are forced to seek and validate a replacement source for any of these critical components.

If our processing and storage facility or our clinical manufacturing facilities are damaged or destroyed, our business and prospects would be negatively affected.

If our processing and storage facility or the equipment in the facility were to be significantly damaged or destroyed, we could suffer a loss of some or all of the stored units of our cell therapy drug candidates and it would force us to delay our clinical trial processes. We have a clinical manufacturing facility located in Haifa, Israel. If this facility or the equipment in it is significantly damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity.

Even if we obtain regulatory approvals to commercialize our cell therapy products, we may encounter a lack of commercial acceptance of our cell therapy products, which would impair the profitability of our business.

Our research and development efforts are primarily directed toward obtaining regulatory approval for our potential cell therapy products. Current methods of stem cell collection and use have been widely practiced for a number of years, and our technology and products may not be accepted by the marketplace as readily as these or other competing processes and methodologies. Additionally, our products may not be employed in all potential applications being investigated, and any reduction in applications would limit the market acceptance of our technology and our potential revenues. As a result, even if we obtain all required regulatory approvals, we cannot be certain that our potential cell therapy products will be adopted at a level that would allow us to operate profitably.

If we do not keep pace with our competitors and with technological and market changes, our technology and products may become obsolete and our business may suffer.

The cellular therapeutics industry, of which we are a part, is very competitive and is subject to technological changes that can be rapid and intense. We have faced, and will continue to face, intense competition from biotechnology, pharmaceutical and biopharmaceutical companies, academic and research institutions and governmental agencies engaged in cellular therapeutic and drug discovery activities or funding, both in the United States and internationally. Some of these competitors are pursuing the development of cellular therapeutics, drugs and other therapies that target the same diseases and conditions that we target in our clinical and preclinical programs.

Many of our competitors have significantly greater resources, more product candidates and have developed product candidates and processes that directly compete with our products. Our competitors may have developed, or could develop in the future, new products that compete with our products or even render our products obsolete.

We depend to a significant extent on certain key personnel, the loss of any of whom may materially and adversely affect our company.

Our success depends on a significant extent to the continued services of certain highly qualified scientific and management personnel, in particular, Zami Aberman, our Chief Executive Officer, and Yaky Yanay, our Chief Financial Officer. We face competition for qualified personnel from numerous industry sources, and there can be no assurance that we will be able to attract and retain qualified personnel on acceptable terms. The loss of service of any of our key personnel could have a material adverse effect on our operations or financial condition. In the event of the loss of services of such personnel, no assurance can be given that we will be able to obtain the services of adequate replacement personnel. We do not maintain key person insurance on the lives of any of our officers or employees.

The patent approval process is complex and we cannot be sure that our pending patent applications or future patent applications will be approved.

The patent approval process is complex and results are therefore highly uncertain. No assurance can be given that any of our pending patent applications or future patent applications will be approved, that the scope of any patent protection granted will exclude competitors or provide us with competitive advantages, that any of the patents that have been or may be issued to us will be held valid if subsequently challenged, or that other parties will not claim rights to or ownership of our patents or other proprietary rights that we hold. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or products or design around any patents that have been or may be issued to us or any future licensors. Since patent applications in the United States are not publicly disclosed until patents are issued, there can be no assurance that others did not first file applications for products covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others pursuant to such applications.

Our success depends in large part on our ability to develop and protect our technology and our cell therapy products. If our patents and proprietary rights agreements do not provide sufficient protection for our technology and our cell therapy products, our business and competitive position will suffer.

Our success will also depend in part on our ability to develop our technology and commercialize cell therapy products without infringing the proprietary rights of others. We have not conducted freedom of use patent searches and no assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to develop our technology or maintain our competitive position with respect to our potential cell therapy products. If our technology components, devices, designs, products, processes or other subject matter are claimed under other existing United States or foreign patents or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our technology or products. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed products or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse affect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development of our technology and the commercialization our potential cell therapy products.

We must further protect and develop our technology and products in order to become a profitable company.

The initial patent underlying our technology will expire in approximately 2020. If we do not complete the development of our technology and products in development by then, or to create additional sufficient layers of patents, other companies may use the technology to develop competing products. If this happens, we would likely lose our competitive position and our business would likely suffer.

Furthermore, the scope of our patents may not be sufficiently broad to offer meaningful protection. In addition, our patents could be successfully challenged, invalidated or circumvented so that our patent rights would not create an effective competitive barrier. We also intend to seek patent protection for any of our potential cell therapy products once we have completed their development.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers and licensees. These agreements may be breached, and we might not have adequate remedies for any breach. If this were to occur, our business and competitive position would suffer.

Potential product liability claims could adversely affect our future earnings and financial condition.

We face an inherent business risk of exposure to product liability claims in the event that the use of our products results in adverse affects. As a result, we may incur significant product liability exposure. We may not be able to maintain adequate levels of insurance at reasonable cost and/or reasonable terms. Excessive insurance costs or uninsured claims would add to our future operating expenses and adversely affect our financial condition.

Our principal research and development facilities are located in Israel and the unstable military and political conditions of Israel may cause interruption or suspension of our business operations without warning.

Our principal research and development facilities are located in Israel. As a result, we are directly influenced by the political, economic and military conditions affecting Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Acts of random terrorism periodically occur which could affect our operations or personnel.

In addition, Israeli-based companies and companies doing business with Israel, have been the subject of an economic boycott by members of the Arab League and certain other predominantly Muslim countries since Israel s establishment. Although Israel has entered into various agreements with certain Arab countries and the Palestinian Authority, and various declarations have been signed in connection with efforts to resolve some of the economic and political problems in the Middle East, we cannot predict whether or in what manner these problems will be resolved. Wars and acts of terrorism have resulted in significant damage to the Israeli economy, including reducing the level of foreign and local investment.

Furthermore, certain of our officers and employees may be obligated to perform annual reserve duty in the Israel Defense Forces and are subject to being called up for active military duty at any time. All Israeli male citizens who have served in the army are subject to an obligation to perform reserve duty until they are between 42 and 54 years old, depending upon the nature of their military service.

Although our internal control over financial reporting was considered effective as of June 30, 2009, there is no assurance that our internal control over financial reporting will continue to be effective in the future, which could result in our financial statements being unreliable, government investigation or loss of investor confidence in our financial reports.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to furnish an annual report by our management assessing the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. Management s report as of the end of fiscal year 2009 concluded that our internal control over financial reporting was effective. There is however, no assurance that we will be able to maintain such effective internal control over financial reporting in the future. Ineffective internal control over financial reporting can result in errors or other problems in our financial statements. In addition, our internal control over financial reporting has not yet been audited by our independent registered public accounting firm. In the future, if we are unable to assert that our internal controls are effective, our investors could lose confidence in the accuracy and completeness of our financial reports, which in turn could cause our stock price to decline. Failure to maintain effective internal control over financial reporting could also result in investigation or sanctions by regulatory authorities.

Because some of our officers and directors are located in non-U.S. jurisdictions, you may have no effective recourse against the management for misconduct and may not be able to enforce judgment and civil liabilities against our officers, directors, experts and agents.

Most of our directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of their assets are located outside the United States. As a result, it may be difficult for you to enforce within the United States any judgments obtained against our officers or directors, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any U.S. state.

Because we do not intend to pay any dividends on our common stock, investors seeking dividend income should not purchase shares of our common stock.

We have not declared or paid any dividends on our common stock since our inception, and we do not anticipate paying any such dividends for the foreseeable future. Investors seeking dividend income should not invest in our common stock.

We have a potential conflict with a prior financing agreement that may expose us to potential litigation

In our subscription agreement for our May 2007 equity financing, or the Prior Financing Agreement, there is a provision that requires us for a period of four years (subject to acceleration under certain circumstances) not to sell any of our common stock for less than $.0125 per share. The Prior Financing Agreement provides that any sale below that number must be preceded by a consent from each purchaser in the placement. Since that date, we have effected a one-for-200 reverse stock split.

In August, 2008, we entered into securities purchase agreements pursuant to which we sold securities at a price higher than the pre-split price of $0.125 and below the post-split price of $2.50. We decided to proceed with this offering notwithstanding this provision for the following reasons:

- The agreement did not contain any provisions for the adjustment of the specified minimum price in the event of stock splits and the like. If such agreement were to have contained such a provision, the floor price would be $2.50, which is more than the offering price of this offering.
- The majority of purchasers in the private placement have sold the stock purchased in the placement, and thus the number of purchasers whose consent is purportedly required has been substantially reduced. The number of shares outstanding as to which this provision currently applies according the information supplied by our transfer agent is 1,848,545 shares.
- An agreement that prevents our Board of Directors from issuing shares that are necessary to finance our business may be unenforceable.
- Even if the agreement were considered enforceable and the share price number were to be adjusted for our reverse stock split, we believe that there would be no damage from this offering to the holders of our shares whose consent is purportedly required.

In the event that a court were to hold that the issuance of shares below $2.50 per share would violate the Prior Financing Agreement, it is unclear what remedy the court might impose. If the court were to impose a remedy that would be the equivalent of an anti-dilution provision (which is not contained in the Prior Financing Agreement), any issuance of shares would be dilutive to our shareholders, including those who purchase shares in the current offering. In addition, since August 2008, we, on several occasions, raised funds at a price per share which is higher than the pre-split price of $0.125 and below the post-split price of $2.50.

In connection with the August, 2008 financing, we approved the issuance of warrants to purchase up to 147,884 shares of our common stock to each of the investors who was a party to the Prior Financing Agreement that held shares purchased pursuant to such agreement, as of August, 2008, conditioned on having the investors execute a general release pursuant to which we will be released from liability including, but not limited to, any claims, demands, or causes of action arising out of, relating to, or regarding sales of certain equity securities notwithstanding the above mentioned provision. As of September 10, 2009 we received a general release from some of the investors, and issued them warrants to purchase 70,368 shares of our common stock

Item 1B. Unresolved Staff Comments.

Not Applicable.

Item 2. Properties.

Our principal offices are located at MATAM Advanced Technology Park, Building No. 20, Haifa, Israel 31905, where we occupy approximately 13,800 square feet. We lease our facilities. Our monthly rental as of September 2009 is 69,000 NIS (approximately $18,000). For the fiscal year ended June 30, 2009, we paid $220,866 for rent. We believe that the space available in our facilities is adequate to meet our current needs, although future growth may require that we occupy additional space.

Item 3. Legal Proceedings.

None.

Item 4. Submissions 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.

On December 19, 2002, our shares of common stock received approval for quotation on the National Association of Securities Dealers Inc. s (now the Financial Regulatory Authority) Over-the-Counter Bulletin Board. On May 7, 2007, our shares also began trading on Europe s Frankfurt Stock Exchange, under the symbol PJT. On November 26, 2007, we effected a two hundred for one reverse stock split. On December 10, 2007, our shares began trading on the NASDAQ Capital Market under the symbol PSTI.

The following table reflects the high and low bid information for our common stock on the OTC Bulletin Board and high and low sale prices on the NASDAQ Capital Market obtained from Yahoo! Finance and reflects inter-dealer prices, without retail mark-up, markdown or commission, and may not necessarily represent actual transactions. All numbers are adjusted for our two hundred for one reverse stock split.

The high and low bid and sale prices of our common stock for the periods indicated below are as follows:

OTC Bulletin Board

Quarter Ended	High	Low
September 30, 2007	$7.8	$7.2

NASDAQ

Quarter Ended	High	Low
December 31, 2007	$4.15	$3.51
March 31, 2008	$1.95	$1.61
June 30, 2008	$1.32	$1.20
September 30, 2008	$0.89	$0.82
December 31, 2008	$0.44	$0.38
March 31, 2009	$1.39	$1.28
June 30, 2009	$1.41	$1.29

On September 10, 2009, the per share closing price of our common stock, as reported by Yahoo! Finance, was $1.44. As of September 10, 2009, there were 110 holders of record of our common stock. As of such date, 15,796,181 common shares were issued and outstanding.

American Stock Transfer and Trust Company, LLC is the registrar and transfer agent for our common shares. Their address is 6201 15th Avenue, 2nd Floor, Brooklyn, NY 11219, telephone: (718) 921-8261, (800) 937-5449.

Dividend Policy

We have not paid any cash dividends on our common stock and have no present intention of doing so. Our current policy is to retain earnings, if any, for use in our operations and in the development of our business. Our future dividend policy will be determined from time to time by our Board of Directors.

Recent Sales of Unregistered Securities

In April 2009, we issued 3,500 shares to a consultant in consideration for services he provided to our company.

In April 2009, we granted 100,000 options exercisable at a price of $1.34 per share to a consultant in consideration for services he provided to our company. The options vest in twelve equal monthly installments of 8,333 shares.

In May 2009, we issued 164,307 shares of common stock to our employees, directors and consultants. The shares were issued in exchange for a one year voluntary reduction in the cash compensation they were entitled to receive in consideration for their services.

In May and June 2009, we issued 5,644 shares of common stock to a media relations consultant in consideration for services he provided to our company.

These issuances were deemed exempt under Regulation S, Regulation D and/or Section 4(2) of the Securities Act of 1933, as amended.

Item 6. Selected financial data.

Not Applicable.

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

Overview:

We develop and intend to commercialize, cell therapy production technologies and products.

On December 10, 2007, our shares of common stock began trading on the NASDAQ Capital Market under the symbol PSTI. The shares were previously traded on the OTC Bulletin Board under the trading symbol PLRS.OB . On May 7, 2007, our shares also began trading on the Frankfurt Stock Exchange, under the symbol PJT.

Effective on July 1, 2008, we amended our Articles of Incorporation to authorize 10,000,000 shares of Preferred Stock, par value $0.00001, with such series, rights, preferences, privileges and restrictions as may be designated from time to time by the Board of Directors.

RESULTS OF OPERATIONS YEAR ENDED JUNE 30, 2009 COMPARED TO YEAR ENDED JUNE 30, 2008.

We have not generated any revenues, and we have negative cash flow from operations of $17,730,000 and have accumulated a deficit of $32,652,000 since our inception in May 2001. This negative cash flow is mostly attributable to research and development and general and administrative expenses. We anticipate that our operating expenses will increase as we intend to conduct expanded development of our products through animal pre-clinical trials and experiments and clinical trials. We estimate our cash expenses in the next twelve months will be approximately $6,000,000, generally falling in two major categories: research and development costs and general and administrative expenses.

Research and Development net

Research and development net costs, for the year ended June 30, 2009 decreased by 28% to $3,141,000 from $4,393,000 for the year ended June 30, 2008. The decrease is due to the decrease in stock-based compensation to employees and consultants in the amount of $1,036,000 as a result of a decrease in our stock price, and due to an increase in the participation by the Israeli Office of the Chief Scientist, or OCS, which offset costs, as the grant for the last 4 months of fiscal year 2008 was approved and recorded in fiscal year 2009. This decrease is partially offset by increasing expenses of subcontractors and materials as we are progressing with our research and development toward clinical trials.

For the next twelve months, we estimate that our cash research and development net costs will be approximately $4,000,000. We intend to spend our research and development funds on continuing research of our PLX cells, continuing our Phase I clinical trials for the PAD indication in the United States and Germany, upgrading the 3-D bioreactor operations, developing the expansion of our placenta adherent stem cell product, and developing capabilities for new clinical indications of PLX cells.

General and Administrative

General and administrative expenses for the year ended June 30, 2009 decreased by 43% to $3,417,000 from $6,036,000 for the year ended June 30, 2008. The decrease in general and administrative expenses is primarily attributable to the decrease in stock-based compensation to employees and consultants in the amount of $1,865,000. In addition, we reduced various expenses, mainly expenses related to services provided by investor relations and public relations consultants.

For the next twelve months, we estimate that our cash general and administrative expenses will be approximately $2,000,000. These expenses will include management services, public relations and investor relations and additional amounts on office and miscellaneous charges, which consist primarily of charges incurred for purchase of office supplies and other administrative expenses. These expenses will also include professional fees, which consist primarily of accounting and auditing fees for the year-end audit and legal fees for securities advice, directors liability insurance and cost of fundraising.

Net Loss

Net loss for the year ended June 30, 2009 was $6,636,000 as compared to net loss of $10,498,000 for the year ended June 30, 2008. Net loss per share for the year ended June 30, 2009 was $0.63, as compared to $1.63 for the year ended June 30, 2008. The net loss per share decreased as a result of the decrease in the net loss and the increase in our weighted average number of shares due to the issuance of additional shares pursuant to equity issuances since July 1, 2008 as discussed further below.

Liquidity and Capital Resources

As of June 30, 2009, total current assets were $2,935,000 and total current liabilities were $840,000. On June 30, 2009, we had a working capital surplus of $2,095,000 and an accumulated deficit of $32,652,000. We finance our operations and plan to continue doing so with stock issuances and with the participation of the OCS.

Cash and cash equivalents as of June 30, 2009 amounted to $2,339,000. This is an increase of $2,016,000 from the $323,000 reported as of June 30, 2008. In addition to the cash and cash equivalents, we had marketable securities in the amount of $1,185,000 as of June 30, 2008. Cash balances increased in the year ended June 30, 2009 for the reasons presented below:

Operating activities used cash of $4,262,000 in the year ended June 30, 2009. Cash used by operating activities in the year ended June 30, 2009 primarily consisted of payments of salaries to our employees, and payments of fees to our consultants, subcontractors and professional services providers, less research and development grant participation by the OCS.

Investing activities provided cash of $830,000 in the year ended June 30, 2009. This resulted primarily from proceeds from sale of marketable securities in the amount of $1,113,000 offset by purchases of capital equipment and leasehold improvements associated with our GMP in the amount of $313,000.

Financing activities generated cash in the amount of $5,448,000 during the year ended June 30, 2009 resulting primarily from receiving cash from investors related to the offerings described below.

On August 6, 2008, we sold 1,391,304 shares of our common stock and warrants to purchase 695,652 shares of common stock at an exercise price of $1.90 per share to two investors in consideration of $1,600,000 pursuant to the terms of a securities purchase agreement. Rodman & Renshaw, LLC acted as placement agent, on a best efforts basis, for the offering and received a placement fee equal to 6% of the gross purchase price of the securities sold (excluding any consideration that may be paid in the future upon exercise of the warrants) as well as warrants to purchase 83,478 shares of common stock at an exercise price of $1.44 per share. Subject to Financial Industry Regulatory Authority, or FINRA, Rule 2710, the placement agent warrants may be exercised after six months through and including August 5, 2013. The offering was made pursuant to our effective shelf registration statement on Form S-3 (File No. 333-151761).

On September 22, 2008, we sold 900,000 shares of our common stock and warrants to purchase 675,000 shares of common stock to an investor in consideration for $1,035,000 pursuant to terms of a securities purchase agreement. The price per share of common stock was $1.15, and the exercise price of the warrants is $1.90. The warrants will be exercisable for a period of five years. The offering was made pursuant to our effective shelf registration statement on Form S-3 (File No. 333-151761). As part of this transaction, we paid a transaction fee to finders equal to 6% of the actual purchase price and issued, for no further consideration, warrants exercisable for five years at an exercise price of $1.50 per share to purchase 54,000 shares of our common stock.

During November 2008 through January 2009, we entered into securities purchase agreements with various investors, pursuant to which we sold in aggregate of 1,746,575 shares of our common stock at a price of $0.40 per share, for an aggregate purchase price of $698,630, and issued warrants to purchase up to an additional 1,746,575 shares of common stock with an exercise price of $1.00 per share. The warrants became exercisable after six months from the applicable closing date and will expire after five years from such date. Pursuant to the securities purchase agreements, the investors had the option, by notice to us no later than 10 business days following the release of an official announcement by us that the company is initiating its first human clinical trials, to purchase an additional 931,507 shares of common stock at a purchase price of $0.75 per share, for an aggregate purchase price of $698,630, and receive therewith warrants to purchase up to additional 931,507 shares of common stock with an exercise price of $1.50 per share, or the Initial Option. The Initial Option was exercisable within six months from the applicable closing date. Investors exercised the Initial Option in July 2009 as described further below. As part of this transaction, we paid a transaction fee to finders in an amount of $38,630 in cash and issued them warrants exercisable for five years at an exercise price of $1.00 per share to purchase 96,579 shares of our common stock.

On January 20, 2009, we sold 216,818 shares of our common stock and warrants to purchase 216,818 shares of common stock to investors in consideration for $95,400 pursuant to terms of a securities purchase agreement. The price per share of common stock was $0.44, and the exercise price of the warrants is $1.00 per share. The warrants became exercisable after six months from the closing date and will expire after five years from such date. Pursuant to the agreement, the investors had the option, by notice to us no later than 10 business days following the release of an official announcement by us that the company is initiating its first human clinical trials, to purchase additional 127,200 shares of common stock at a purchase price of $0.75 per share, for an aggregate purchase price of $95,400, and receive therewith warrants to purchase up to an additional 127,200 shares of common stock with an exercise price of $1.50 per share, or the January 20 Option. The January 20 Option was exercisable within six months from the closing date. Investors exercised the January 20 Option in July 2009 as described further below. As part of this transaction, we paid a transaction fee to finders in an amount of $5,400 in cash and issued them warrants exercisable for two years at an exercise price of $1.00 per share to purchase 12,273 shares of our common stock.

On January 29, 2009, we entered into a subscription agreement with certain investors, pursuant to which we sold to such investors 969,826 units, each unit consisting of one share of common stock and a warrant to purchase one share of our common stock exercisable 181 days following the issuance thereof for a period of five years thereafter at an exercise price of $1.90 per share, or the Units. The purchase price per Unit was $1.16 and the aggregate purchase price for such Units was $1,125,000. As part of this transaction, we paid a transaction fee to finders in an amount of $89,546 in cash and issued these investors warrants to purchase 80,983 shares of our common stock, exercisable after six months for five years at an exercise price of $1.90 per share.

On May 5, 2009, we entered into securities purchase agreements with two investors pursuant to which we sold 888,406 shares of our common stock and warrants to purchase 488,623 shares of common stock in consideration for $1,332,610. The exercise price of the warrants is $1.96 and they will be exercisable for a period of five years commencing six months following the issuance thereof. Rodman & Renshaw, LLC acted as placement agent, on a best efforts basis, for the offering and received a placement fee equal to 6% of the gross purchase price of the securities sold (excluding any consideration that may be paid in the future upon exercise of the warrants) as well as warrants to purchase 53,304 shares of common stock at an exercise price of $1.875 per share. Subject to FINRA Rule 2710, the placement agent s warrants may be exercised after six months through and including May 5, 2014. The offering was made pursuant to our effective shelf registration statement on Form S-3 (File No. 333-151761).

We announced that the company is initiating its first human clinical trials, which triggered the ability to exercise the Initial Option and the January 20 Option by certain investors. Accordingly, we issued in July 2009 1,058,708 shares of common stock at a purchase price of $0.75 per share, for an aggregate purchase price of $794,030, and warrants to purchase up to an additional 1,058,708 shares of common stock with an exercise price of $1.50 per share.

We received $1,375,000 from grants from the OCS during the year ended June 30, 2009. Recently, a grant in an amount of $2.3 million was approved for participation in R&D expenses for the period March 2009 to February 2010 (In August 2009 we received $668,000 on account of the approved grant).

While most of our capital resources are denominated by US dollars, about half of our expenses are denominated by NIS. Over the past year, due to the increased volatility of the US Dollar, we began using foreign currency forward contracts. We continue to actively utilize currency hedging transactions to manage our exposure.

Outlook

We do not expect to generate any revenues from sales of products in the next twelve months. We may generate revenues from sale of licenses to use our technology or products. Our products will likely not be ready for sale for at least three years, if at all.

The OCS has supported our activity in the past three years. Our application for a fourth year s grant was submitted in March 2009. Recently, the OCS approved a grant in an amount of $2.3 million for participation in R&D expenses for the period March 2009 to February 2010. We believe that the funds we have, together with the approved R&D grant, will be sufficient for operating until March 2010. Our independent registered public accounting firm s report states that there is a substantial doubt that we will be able to continue as a going concern. Management believes that we will need to raise additional funds before we have any cash flow from operations.

We are looking constantly for sources of funding, including non-diluting funds, such as the OCS grants and filing grant applications with the U.S. National Institutes of Health, which we have done recently. There can be no assurance that we will receive this grant. In addition, we plan to raise additional funds by issuance of equity.

If we are unable to obtain the financing necessary to support our operations, we may need to take measures to reduce our operating costs, or, if such measures will not be sufficient, we may be unable to continue as a going concern. In that event, we may be forced to cease operations and our stockholders could lose their entire investment in the company.

Application of Critical Accounting Policies

Our financial statements and accompanying notes are prepared in accordance with U.S. GAAP. Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses. These estimates and assumptions are affected by management s application of accounting policies. We believe that understanding the basis and nature of the estimates and assumptions involved with the following aspects of our consolidated financial statements is critical to an understanding of our financials.

Stock-based compensation

We account for stock-based compensation in accordance with Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), Share-Based Payment , or SFAS No. 123(R). SFAS No. 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 an expense over the requisite service periods in our consolidated income statements.

We recognize compensation expenses for the value of its awards, which have graded vesting based on the accelerated method over the requisite service period of each of the awards.

We estimate the fair value of stock options granted using the Black-Scholes-Merton option-pricing model. The option-pricing model requires a number of assumptions, of which the most significant are, expected stock price volatility, and the expected option term. Expected volatility was calculated based upon actual historical stock price movements over the most recent periods ending on the grant date. The expected life of options granted is calculated using the Simplified Method, as defined in Staff Accounting Bulletin, or SAB No. 107, Share-Based Payments , or SAB No. 107, as the average between the vesting period and the contractual life of the options. On December 21, 2007 the SEC staff issued SAB No. 110, or SAB 110, which, effective January 1, 2008, amends and replaces SAB No. 107.

We currently use the Simplified Method, as adequate historical experience is not available to provide a reasonable estimate. We adopted SAB 110 effective January 1, 2008 and will continue to apply the Simplified Method until enough historical experience is available to provide a reasonable estimate of the expected term for stock option grants.

We have historically not paid dividends and has no foreseeable plans to issue dividends. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent term. The expected annual pre-vesting forfeiture rate affects the number of exercisable options. Based on our historical experience, the annual pre-vesting forfeiture rate is 5%.

The assumptions below are relevant to restricted shares granted in 2009:

In accordance with SFAS No. 123(R), restricted shares are measured at their fair value as if they were vested and issued on the grant date. All restricted shares to employees and non-employees granted in 2009 were granted for no consideration; therefore their fair value was equal to the share price at the date of grant.

The fair value of all restricted shares was determined based on the close trading price of our shares known at the grant date.

We apply SFAS No. 123 (R) and Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services , with respect to options and warrants issued to non-employees. SFAS 123(R) requires the use of option valuation models to measure the fair value of the options and warrants at the measurement date.

Off Balance Sheet Arrangements

Our company has no off balance sheet arrangements.

Item7A. Quantitative and Qualitative Disclosures About Market Risk.

Not Applicable.

Item 8. Financial Statements and Supplementary Data.

Our financial statements are stated in thousands United States dollars (US$) and are prepared in accordance with U.S. GAAP.

The following audited consolidated financial statements are filed as part of this registration statement:

Report of Independent Registered Public Accounting Firm, dated September 23, 2009

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Changes in Stockholders Equity (Deficiency)

Consolidated Statements of Cash Flows

Notes to the Consolidated Financial Statements

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED FINANCIAL STATEMENTS

As of June 30, 2009

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)
CONSOLIDATED FINANCIAL STATEMENTS

As of June 30, 2009

U.S. DOLLARS IN THOUSANDS

INDEX

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To The Stockholders Of

PLURISTEM THERAPEUTICS INC.

(A Development Stage Company)

We have audited the accompanying consolidated balance sheets of Pluristem Therapeutics Inc. and its subsidiary (a development stage company) (the Company) as of June 30, 2009 and the related consolidated statements of operations, changes in stockholders equity and cash flows for each of the three years in the period ended June 30, 2009 and for the period from May 11, 2001 (inception date) through June 30, 2009. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above, present fairly, in all material respects, the consolidated financial position of the Company as of June 30, 2009, and the consolidated results of operations and cash flows for each of the three years in the period ended June 30, 2009 and for the period from May 11, 2001 (inception date) through June 30, 2009, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1b to the consolidated financial statements, the Company has not yet generated revenues from its operations and is dependent on external sources for financing its operations. These factors, among others discussed in Note 1b, raise substantial doubt about the Company s ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

/s/ Kost Forer Gabbay & Kasierer

Kost Forer Gabbay & Kasierer
A member of Ernst & Young Global

Haifa, Israel
September 23, 2009

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

U.S. Dollars in thousands

	Note	June 30, 2009	June 30, 2008
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	3	$ 2,339	$ 323
Marketable securities	4		1,185
Prepaid expenses		100	350
Accounts receivable from the Office of the Chief Scientist		383	119
Other accounts receivable		113	130
Total current assets		2,935	2,107
LONG-TERM ASSETS:			
Long-term deposits and restricted deposits		171	201
Severance pay fund		154	127
Property and equipment, net	5	1,203	1,149
Total long-term assets		1,528	1,477
Total assets		$ 4,463	$ 3,584

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

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

	Note	June 30, 2009	June 30, 2008
LIABILITIES AND STOCKHOLDERS EQUITY			
CURRENT LIABILITIES			
Trade payables		$ 487	$ 622
Accrued expenses		81	154
Other accounts payable	6	272	296
Total current liabilities		840	1,072
LONG-TERM LIABILITIES			
Long-term obligation		23	36
Accrued severance pay		206	147
		229	183
COMMITMENTS AND CONTINGENCIES	7		
STOCKHOLDERS EQUITY	8		
Share capital:			
Common stock $0.00001 par value:			
Authorized: 30,000,000 shares.			
Issued: 14,738,693 shares, outstanding: 13,676,886 shares as of June 30, 2009.			
Issued and outstanding: 6,941,715 shares as of June 30, 2008.		- (*)	- (*)
Additional paid-in capital		36,046	28,345
Accumulated deficit during the development stage		(32,652)	(26,016)
		3,394	2,329
		$ 4,463	$ 3,584

(*) Less than $1.

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Note	Year ended June 30,			Period from May 11, 2001 (Inception) through June 30,
		2009	2008	2007	2009
Research and development expenses		$ 4,792	$ 5,077	$ 3,084	$ 17,157
Less participation by the Office of the Chief Scientist		(1,651)	(684)	(535)	(3,250)
Research and development expenses,net		3,141	4,393	2,549	13,907
General and administrative expenses		3,417	6,036	3,726	17,373
Know how write-off				1,963	2,474
Gross loss		(6,558)	(10,429)	(8,238)	(33,754)
Financial expenses (income), net	9	78	69	191	(1,102)
Net loss for the period		$ (6,636)	$ (10,498)	$ (8,429)	$ (32,652)
Loss per share:					
Basic and diluted net loss per share		$ (0.63)	$ (1.63)	$ (5.84)	
Weighted average number of shares used in computing basic and diluted net loss per share:		10,602,880	6,422,364	1,442,367	

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY)

U.S. Dollars in thousands (except share data)

	Common Stock		Additional Paid-in Capital	Receipts on Account of Common Stock	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficiency)
	Shares	Amount				
Issuance of common stock on July 9, 2001	175,500	$ (*)	$ 3	$	$	$ 3
Balance as of June 30, 2001	175,500	(*)	3			3
Net loss					(78)	(78)
Balance as of June 30, 2002	175,500	(*)	3		(78)	(75)
Issuance of common stock on October 14, 2002, net of issuance expenses of $17	70,665	(*)	83			83
Forgiveness of debt			12			12
Stock cancelled on March 19, 2003	(136,500)	(*)	(*)			
Receipts on account of stock and warrants, net of finders and legal fees of $56				933		933
Net loss					(463)	(463)
Balance as of June 30, 2003	109,665	$ (*)	$ 98	$ 933	$ (541)	$ 490

(*) Less than $1.

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY)

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

	Common Stock		Additional Paid-in Capital	Receipts on Account of Common Stock	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficiency)
	Shares	Amount				
Balance as of July 1, 2003	109,665	$ (*)	$ 98	$ 933	$ (541)	$ 490
Issuance of common stock on July 16, 2003, net of issuance expenses of $70	3,628	(*)	1,236	(933)		303
Issuance of common stock on January 20, 2004	15,000	(*)				(*)
Issuance of warrants on January 20, 2004 for finder s fee			192			192
Common stock granted to consultants on February 11, 2004	5,000	(*)	800			800
Stock based compensation related to warrants granted to consultants on December 31, 2003			358			358
Exercise of warrants on April 19, 2004	1,500	(*)	225			225
Net loss for the year					(2,011)	(2,011)
Balance as of June 30, 2004	134,793	$ (*)	$ 2,909	$	$ (2,552)	$ 357

(*) Less than $1.

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY)

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

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficiency)
	Shares	Amount			
Balance as of July 1, 2004	134,793	$ (*)	$ 2,909	$ (2,552)	$ 357
Stock-based compensation related to warrants granted to consultants on September 30, 2004			162		162
Issuance of common stock and warrants on November 30, 2004 related to the October 2004 Agreement net of issuance costs of $29	16,250	(*)	296		296
Issuance of common stock and warrants on January 26, 2005 related to the October 2004 Agreement net of issuance costs of $5	21,500	(*)	425		425
Issuance of common stock and warrants on January 31, 2005 related to the January 31, 2005 Agreement	35,000	(*)			(*)
Issuance of common stock and options on February 15, 2005 to former director of the Company	250	(*)	14		14
Issuance of common stock and warrants on February 16, 2005 related to the January 31, 2005 Agreement	25,000	(*)			(*)

(*) Less than $1.

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY)

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

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficiency)
	Shares	Amount			
Issuance of warrants on February 16, 2005 for finder fee related to the January 31, 2005 Agreement			144		144
Issuance of common stock and warrants on March 3, 2005 related to the January 24, 2005 Agreement net of issuance costs of $24	60,000	(*)	1,176		1,176
Issuance of common stock on March 3, 2005 for finder fee related to the January 24, 2005 Agreement	9,225	(*)	(*)		
Issuance of common stock and warrants on March 3, 2005 related to the October 2004 Agreement net of issuance costs of $6	3,750	(*)	69		69
Issuance of common stock and warrants to the Chief Executive Officer on March 23, 2005	12,000	(*)	696		696
Issuance of common stock on March 23, 2005 related to the October 2004 Agreement	1,000	(*)	20		20

(*) Less than $1.

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY)

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

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficiency)
	Shares	Amount			
Classification of a liability in respect of warrants to additional paid in capital, net of issuance costs of $ 178			542		542
Net loss for the year				(2,098)	(2,098)
Balance as of June 30, 2005	318,768	(*)	6,453	(4,650)	1,803
Exercise of warrants on November 28, 2005 to finders related to the January 24, 2005 agreement	400	(*)			
Exercise of warrants on January 25, 2006 to finders related to the January 25, 2005 Agreement	50	(*)			
Reclassification of warrants from equity to liabilities due to application of EITF 00-19			(8)		(8)
Net loss for the year				(2,439)	(2,439)
Balance as of June 30, 2006	319,218	$ (*)	$ 6,445	$ (7,089)	$ (644)

(*) Less than $1.

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY)

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

	Common Stock		Additional Paid-in Capital	Receipts on Account of Common Stock	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders Equity
	Shares	Amount					
Balance as of July 1, 2006	319,218	$ (*)	$ 6,445	$	$	$ (7,089)	$ (644)
Conversion of convertible debenture, net of issuance costs of $440	1,019,815	(*)	1,787				1,787
Classification of a liability in respect of warrants			360				360
Classification of deferred issuance expenses			(379)				(379)
Classification of a liability in respect of options granted to non-employees consultants			116				116
Compensation related to options granted to employees and directors			2,386				2,386
Compensation related to options granted to non-employees consultants			938				938
Exercise of warrants related to the April 3, 2006 agreement net of issuance costs of $114	75,692	(*)	1,022				1,022

(*) Less than $1.

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY)

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

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Receipts on Account of Common Stock	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders Equity	Total Comprehensive Loss
Cashless exercise of warrants related to the April 3, 2006 agreement	46,674	(*)	(*)					
Issuance of common stock on May and June 2007 related to the May 14, 2007 agreement, net of issuance costs of $64	3,126,177	(*)	7,751				7,751	
Receipts on account of shares				368			368	
Cashless exercise of warrants related to the May 14, 2007 issuance	366,534	(*)	(*)					
Issuance of warrants to investors related to the May 14, 2007 agreement			651				651	
Unrealized loss on available for sale securities					(30)		(30)	$ (30)
Net loss for the year						(8,429)	(8,429)	(8,429)
Balance as of June 30, 2007	4,954,110	$ (*)	$ 21,077	$ 368	$ (30)	$ (15,518)	$ 5,897	
Total comprehensive loss								$ (8,459)

(*) Less than $1.

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY)

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

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Receipts on Account of Common Stock	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders Equity	Total Comprehensive Loss
Balance as of July 1, 2007	4,954,110	$ (*)	$ 21,077	$ 368	$ (30)	$ (15,518)	$ 5,897	
Issuance of common stock related to investors relation agreements	69,500	(*)	275				275	
Issuance of common stock in July 2007 - June 2008 related to the May 14, 2007 Agreement	908,408	(*)	2,246	(368)			1,878	
Cashless exercise of warrants related to the May 14, 2007 Agreement	1,009,697	(*)	(*)					
Compensation related to options granted to employees and directors			4,204				4,204	
Compensation related to options granted to non employees consultants			543				543	
Realized loss on available for sale securities					30		30	$ 30
Net loss for the year						(10,498)	(10,498)	(10,498)
Balance as of June 30, 2008	6,941,715	$ (*)	$ 28,345	$	$	$ (26,016)	$ 2,329	
Total comprehensive loss								$ (10,468)

(*) Less than $1.

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIENCY) (UNAUDITED)

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

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders Equity
	Shares	Amount			
Balance as of July 1, 2008	6,941,715	$ (*)	$ 28,345	$ (26,016)	$ 2,329
Issuance of common stock related to investor relations agreements	171,389	(*)	133		133
Issuance of common stock and warrants related to the August 6, 2008 agreement, net of issuance costs of $125	1,391,304	(*)	1,475		1,475
Issuance of common stock and warrants related to the September 2008 agreement, net of issuance costs of $62	900,000	(*)	973		973
Issuance of common stock and warrants in November 2008 - January 2009, net of issuance costs of $39	1,746,575	(*)	660		660
Issuance of common stock and warrants related to the January 20, 2009 agreement, net of issuance costs of $5	216,818	(*)	90		90
Issuance of common stock and warrants related to the January 29, 2009 agreement, net of issuance costs of $90	969,826	(*)	1,035		1,035
Issuance of common stock and warrants related to the May 5, 2009 agreement, net of issuance costs of $104	888,406	(*)	1,229		1,229
Compensation related to options granted to employees and directors			1,315		1,315
Compensation related to options and warrants granted to non employees consultants			97		97
Compensation related to restricted stock granted to employees and directors	427,228	(*)	642		642
Compensation related to restricted stock granted to non employees consultants	23,625	(*)	52		52
Net loss for the period				(6,636)	(6,636)
Balance as of June 30, 2009	13,676,886	$ (*)	$ 36,046	$ (32,652)	$ 3,394

(*) Less than $1.

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. Dollars in thousands

	Year ended June 30,			Period from May 11, 2001 (inception) through June 30
	2009	**2008**	**2007**	**2009**
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (6,636)	$ (10,498)	$ (8,429)	$ (32,652)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	173	129	56	545
Capital loss			20	4
Impairment of property and equipment	5	47		52
Know-how write-off			1,963	2,474
Amortization of deferred issuance costs			168	604
Stock-based compensation to employees and directors	1,957	4,204	2,386	8,547
Stock-based compensation to non-employees consultants	149	561	920	2,298
Stock compensation to service providers and investor relations consultants	133	275		1,200
Know-how licensors imputed interest				55
Salary grant in shares and warrants				711
Decrease (increase) in other accounts receivable	(247)	336	(481)	(485)
Decrease (increase) in prepaid expenses	250	(308)	20	(10)
Increase (decrease) in trade payables	(54)	237	(1)	457
Increase (decrease) in other accounts payable and accrued expenses	(96)	74	189	(135)
Increase in accrued interest due to related parties				3
Linkage differences and interest on long-term restricted lease deposit				(2)
Change in fair value of liability in respect of warrants			(716)	(2,696)
Fair value of warrants granted to investors			651	651
Amortization of discount and changes in accrued interest on convertible debentures			111	128
Amortization of discount and changes in accrued interest from marketable securities	(3)	(1)	(5)	(9)
Loss from sale of investments of available-for-sale marketable securities	75	31		106
Impairment and realized loss on available-for-sale marketable securities		372		372
Accrued severance pay, net	32	4	(4)	52
Net cash used in operating activities	$ (4,262)	$ (4,537)	$ (3,152)	$ (17,730)

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

PLURISTEM THERAPEUTICS INC. AND ITS SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. Dollars in thousands

	Year ended June 30,			Period from May 11, 2001 (inception) through June 30
	2009	**2008**	**2007**	**2009**
CASH FLOWS FROM INVESTING ACTIVITIES:				
Acquisition of Pluristem Ltd. (1)	$	$	$	$ 32
Purchase of property and equipment	(313)	(840)	(209)	(1,605)
Proceeds from sale of property and equipment		3	1	32
Investment in long-term deposits	(8)	(85)	(96)	(217)
Repayment of long-term restricted deposit	38	6		64
Purchase of available for sale marketable securities			(3,784)	(3,784)
Proceeds from sale of available for sale marketable securities	1,113	2,201		3,314
Purchase of know-how			(1,963)	(2,062)
Net cash provided by (used in) investing activities	830	1,285	(6,051)	(4,226)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Issuance of common stock and warrants, net of issuance costs	5,462	$ 2,246	$ 7,751	21,391
Receipts on account of shares		(368)	368	
Exercise of warrants			1,022	1,022
Issuance of convertible debenture				2,584
Issuance expenses related to convertible debentures			(440)	(440)
Repayment of know-how licensors			(219)	(300)
Repayment of notes and loan payable to related parties				(70)
Proceeds from notes and loan payable to related parties				78
Receipt of long-term loan		49		49
Repayment of long-term loan	(14)	(5)		(19)
Net cash provided by financing activities	5,448	1,922	8,482	24,295
Increase (decrease) in cash and cash equivalents	2,016	(1,330)	(721)	2,339
Cash and cash equivalents at the beginning of the period	323	1,653	2,374	
Cash and cash equivalents at the end of the period	$ 2,339	$ 323	$ 1,653	$ 2,339
(a) Supplemental disclosure of cash flow activities:				
Cash paid during the period for:				
Taxes paid due to non-deductible expenses	$ 33	$ 5	$ 3	$ 47

Interest paid	$ 3	$ 3