AI SOFTWARE INC
Form 8-K
June 25, 2003

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **June 10, 2003**

A.I. SOFTWARE, INC.
(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation)

333-69176

(Commission File Number)

98-0351734

(IRS Employer Identification No.)

1030 West Georgia Street, Suite 1208, Vancouver, BC, Canada, V6E 2Y3

(Address of principal executive offices and Zip Code)

Registrant's telephone number, including area code

(604) 662-7900

Item 2. Acquisition or Disposition of Assets

Introduction

Pursuant to a share purchase agreement dated June 10, 2003, we have acquired 100% of the issued and outstanding shares of Pluristem Ltd. ("Pluristem") from Abramovich Trust Company Ltd. In consideration for acquiring all of the Pluristem shares we have paid to Abramovich Trust Company Ltd. cash in the amount of US$1,000 and provided Pluristem with a line of credit in the amount of US$500,000. Accordingly, Pluristem became our wholly-owned subsidiary as of June 10, 2003.

DESCRIPTION OF BUSINESS

As used in this current report, the terms "we", "us", "our", and "AI Software" mean AI Software, Inc. and our wholly-owned subsidiary, Pluristem Ltd., unless otherwise indicated.

All dollar amounts refer to US dollars unless otherwise indicated.

Corporate History

AI Software was incorporated in the State of Nevada on May 11, 2001. Since July 2001, we have been engaged in software development. Our business plan is premised on the use of artificial intelligence in computer programming technology and in many areas of the computer, Internet, robotics, and games industries. On July 1, 2001 we entered into a software development agreement with Empire Group, a software development firm which specializes in the development of artificial intelligence software. Pursuant to the terms of the software development agreement, Empire Group was to develop for us the software algorithm program for an artificial intelligence software called "Randomix." This proposed artificial intelligence program, Randomix, is intended to use pattern recognition in the context of a domain name creation engine for online businesses. A domain name creation engine is essentially a website that assists computer users in picking website names which are meaningful to them. By inputting criteria into the computer that are relevant to the user's business, Randomix will use pattern recognition to generate available domain names which are relevant to the criteria entered. Pattern recognition involves recognizing and detecting patterns and trends in a given set of data. A demonstration version of Randomix was completed by Empire Group in May of 2002 but we have not yet completed the development of the Randomix software.

Recent Developments

To date we have not been successful in fully implementing our business plan in regards to our Randomix software. As a result, our Board of Directors has conducted an in-depth analysis of our business plan and related future prospects for software development companies. To better protect stockholder interests and provide future appreciation, it was decided to concurrently pursue initiatives in the biotech industry as an extension to our existing business. Accordingly, we have been researching potential acquisitions or other suitable business partners which will assist us in realizing our overall business objectives. We felt that this was in the best interests of the company given the fact that it was becoming less likely that our software could be developed into a profitable business.

On May 5, 2003, we entered into a License Agreement (the "License Agreement")with the Weizmann Institute of Science and the Technion-Israel Institute of Technology to acquire an exclusive license for a stem cell expansion technology. This technology offers promising, novel solutions related to bone marrow transplants.

To be able to develop the exclusive license for the stem cell expansion technology, we purchased 100% of the issued and outstanding shares of a research and development company based in Israel called Pluristem Ltd. ("Pluristem") on June 10, 2003, from Abramovich Trust Company Ltd. Pluristem was incorporated under the law of Israel on 22 January of 2003 and has the facilities and personnel to conduct research and development in the field of stem cell research. As consideration for the shares of Pluristem, we paid to Abramovich Trust Company Ltd. cash in the amount of US$1,000 and provided Pluristem with a line of credit in the amount of US$500,000. Accordingly, Pluristem became our wholly-owned subsidiary as of June 10, 2003.

Business of Pluristem

With the acquisition of Pluristem, we aim to become a leader in stem cell expansion, specializing initially in the expansion of hematopoietic stem cells found in umbilical cord blood, using the technology platform we recently acquired under the License Agreement.

Furthermore, we believe that Pluristem's stromal cell expression libraries can be expected to booster bone marrow transplants and significantly improve their success rates while maximizing immune system functioning.

Pluristem will conduct further research and development in our key technology, the PluriX™ Bioreactor, which is a system of stromal cell cultures and substrates that create an artificial physiological environment in which hematopoietic stem cells can grow and reproduce. Scientists have developed sufficient understanding to actually use these hematopoietic stem cells for cell therapy and bone marrow transplants for the potential treatment of a broad range of complicated diseases.

Brief Introduction of Stem Cell Research and Cell Therapy

Since 1998, when embryonic human stem cells were first isolated, research on stem cells has received much public attention. Stem cells have two important characteristics that distinguish them from other types of cells. First, they are unspecialized cells that renew themselves for long periods through cell division. Second, under certain physiologic or experimental conditions, stem cells can be induced to become cells with special functions, such as the beating cells of the heart muscle or the insulin-producing cells of the pancreas.

Scientists primarily work with two kinds of stem cells from animals and humans: embryonic stem cells and adult stem cells, which have different functions and characteristics. In some adult tissues, such as bone marrow, muscle, and brain, discrete populations of adult stem cells generate replacements for cells that are lost through normal wear and tear, injury, or disease.

Cell therapy is the use of living cells in the treatment of medical disorders. Stem cells, progenitors and differentiated functional cells of various tissues are evolving as potential treatment modality for life threatening diseases and major clinical indications lacking effective cures. Cell therapy is still in its very beginning stages of research and development and only a few potential products are already in clinical studies. The number of approved cell therapy products in the market is even smaller.

Even though we have the capability to work with embryonic stem cells, we have chosen to concentrate our efforts on hematopoietic stem cells. Hematopoietic Stem Cells can usually be found in every adult's bone marrow, which is the spongy tissue found in the cavities of our bones. Hematopoietic stem cells are the precursors of the various types of blood cells in the human body. These cells include:

- White cells that fight infections and inflammations (leukocytes) and form the basis of the immune system (lymphocytes);

- Red cells that carry oxygen through our bodies (erythrocytes); and

- Platelets that help blood to clot.

As noted above, scientists have developed sufficient understanding to actually use hematopoietic stem cells for therapy, such as through the procedure of bone marrow transplant. Thus, this class of human stem cell holds the promise of being able to repair or replace cells or tissues that are damaged or destroyed by many of our most devastating diseases and disabilities. Furthermore, bone marrow transplants are ultimate treatments in many pathological situations, including:

- Malignant blood system diseases, such as leukemia, lymphoma and myaloma,

- Diseases of lack of, or defective, production of bone marrow, such as aplastic anemia,

- Severe combined immune deficiency (SCID),

- Non-hematopoietic malignancies (solid tumors), or bone marrow disorders, following chemotherapy and radiation, and

- Metabolic diseases or congenital hemoglobinopathies, e.g., thalessemia.

Within the hematopoietic system, pluripotent hematopoietic stem cells are the only cells with extensive capacities to expand, differentiate and self-renew. Pluripotent hematopoietic stem cells are exclusively required for hematopoietic reconstitution following transplantation. In spite of the key role of pluripotent hematopoietic stem cells in maintaining the hematopoietic system, their extremely low frequency in the hematopoietic tissue, as well as the limited ability to maintain or expand undifferentiated stem cells outside of a patient's body, not only remains a major drawback to essential clinical applications of these cells, but also reflects the current unavailability of, and the need for, novel stem cell regulators. In spite of all the challenges involved in hematopoietic stem cell transplants, physicians are now trying, sometimes successfully, to assist in hematopoietic and immune system recovery following high-dose chemotherapy and/or radiation therapy treatment for malignant and non-malignant diseases such as leukemia and certain immune and genetic disorders. For stem cell transplants to succeed, the donated stem cells must repopulate and/or engraft the recipient's bone marrow, where they will provide a new source of essential blood and immune system cells.

Brief Introduction of Bone Marrow Transplants

The bone marrow transplant procedure involves three phases. In the first phase, lasting 5 to 14 days, the bone marrow recipient is prepared for the graft. Immunosuppressive and cytotoxic chemotherapy administered with or without irradiation are used to enable the recipient to accept the graft, to prevent graft rejection, and in cases of acute leukemia, to eliminate residual leukemia.

In the second phase, bone marrow is procured from a compatible donor and intravenously administered to the graft recipient.

The third phase is a period of waiting for the bone marrow to engraft and function normally in the recipient. During the time required for engraftment (approximately 2 to 4 weeks), the graft recipient is vulnerable to infection, bleeding, severe weight loss, rejection of the graft and graft-versus-host disease. Graft-versus-host disease occurs in approximately 50% of bone marrow transplant patients. If the marrow engrafts and the patient survives the immediate post-transplant period (first 3 to 6 weeks), the patient faces another set of complications, including graft-versus-host disease and interstitial pneumonia. Interstitial pneumonia occurs in 60% of bone marrow transplant patients, typically 4 to 6 weeks post transplant. The disease progresses rapidly and is fatal in approximately 50% of the cases. 50%-60% of patients survive where the bone marrow transplant is made during disease remission, and only 10%-25% survive in cases where the bone marrow transplant is done outside of remission. (Source: The Cost Effectiveness of BMT Therapy and Its Policy Implications, School of Public Health, UCLA).

There are several types of bone marrow transplants. They are distinguished according to the source of the stem cells. An autologus bone marrow transplant means the transplant stem cells come from the patient. An allogenic bone marrow transplant means the stem cells come from a donor. A syngeneic bone marrow transplant means the stem cells come from an identical twin.

Research and clinical work in the field of bone marrow transplants is presently limited due to:

- The average number of active hematopoietic stem cells in any given bone marrow is extremely low (less than 0.5%) of total cells;

- The difficulties of the human body to accept bone marrow transplants from donors, and the ensuing damaging reactions;

- The patient is quite prone to infections following radiation and/or chemotherapy treatments, and may have been infected even prior to the transplant;

- Sorting of healthy cells from cancerous cells has not proven 100% successful, meaning that the bone marrow transplant can end up replacing cancerous cells with more cancerous cells, in the case that the transplant stem cells are autologus;

- The great complications in storing and enriching these cells in the absence of *in vitro* differentiation;

- The absence of a large-scale and sustainable model that enables the testing of the ability of hematopoietic stem cells to renew the hematopoietic system; and

- There are some clinical situations where autologus bone marrow after tumor purging provides insufficient numbers of hematopoietic stem cells for the bone marrow transplant.

Transplantation experts believe that the ideal approach to a successful stem cell transplant is to use a large number of stem cells to maximize the probability of bone marrow repopulation and minimize the time needed for the return of normal numbers of hematopoietic and immune cells in the patient.

One of the major efforts in developing hematopoietic stem cell technologies has been to identify new and better sources for stem cells. The majority of transplantable hematopoietic stem cell in adults currently comes primarily from peripheral blood or adult donor bone marrow. Another important and attainable source of transplantable and lasting hematopoietic stem cells is from umbilical cord blood. Such blood is drawn from the umbilical cord after birth, but before the discharge of the placenta, giving way to the following advantages:

- The standard procedure at birth is that umbilical cord blood is discarded with the placenta. No morbidity is involved, making this option free of ethical controversy.

- Collection of umbilical cord blood is simple and non-invasive both to the mother and the baby;

- Use of umbilical cord blood is already U.S. Federal Drug Administration ("FDA") approved and does not require further clinical testing;

- The hematopoietic stem cells drawn from umbilical cord blood can differentiate into primary hematopoietic precursors and create hematopoietic clones in cultures better than those hematopoietic stem cells taken from adult bone marrow;

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Umbilical cord blood has lower levels of contamination with common viral pathogens, such as Cytomegalovirus, and is more tolerant of alloantigens; and

- Umbilical cord blood hematopoietic stem cells have high tolerance levels, giving way to lower graft-versus-host diseases.

It is important to note that scientists have found no difference in the functionality of hematopoietic stem cells drawn from bone marrow, peripheral blood or umbilical cord blood. However, owing to the small volume of blood collected from umbilical cords (typically less than 100 ml), use of umbilical cord blood has been limited to date to transplants in babies and children weighing under 45 kg. Moreover, there are no existing hematopoietic stem cell expansion technologies for umbilical cord blood that can increase to the best of our knowledge the number of hematopoietic stem cells without causing differentiation of the hematopoietic stem cells. Once the hematopoietic stem cells have

differentiated, they cannot be transplanted into the patient. Therefore, the development of a system that will facilitate the proliferation of hematopoietic stem cells in an appropriate culture media or substrate could enable the use of such hematopoietic stem cells drawn from umbilical cord blood for transplanting in adults where insufficient hematopoietic stem cells are available.

In summary, transplants of hematopoietic stem cells derived from umbilical cord blood are a novel alternative to conventional bone marrow transplants and have several unique advantages, in spite of their present quantitative limitations. Umbilical cord blood lends itself to sorting and storing in cord blood banks and transplant clinics, leading to the ability to build data bases of expanded umbilical cord blood for national and worldwide access and use, making search of bone marrow transplant donors easily facilitated and making autologous bone marrow transplants in adults potentially feasible. We believe that the advantages in use of umbilical cord blood hematopoietic stem cells, combined with our platform technology have the potential to change the ways bone marrow transplants are conducted in the future.

Our Core Technology and PluriX™ Bioreactor System

For decades, scientists have attempted to "grow" stem cells in culture to increase the number of stem cells for transplantation. The challenge of this undertaking lies in overcoming stem cells' predisposition to differentiate. Adult hematopoietic stem cells tend to produce other cells with limited repopulating properties when grown in culture rather than to replicate and regenerate additional stem cells. Current stem cell expansion techniques are complicated by the diverse mix of differentiated cells generated in stem cell cultures. Existing scientific methods considered in increasing the number of stem cells include culturing the stem cells on two dimensional stromal layers and growing in the presence of cytokines. To the best of our knowledge, none of these existing methods to grow stem cells outside of patients' bodies are able to prevent differentiation of stem cells while promoting their proliferation.

Through the License Agreement and the acquisition of Pluristem we have acquired a process, a three dimensional bioreactor, called PluriX™, which has the potential to bring about the expansion of umbilical cord blood hematopoietic stem cells to proportions that will be enough for a number of adult transplants, without promoting differentiation.

The PluriX™ Bioreactor system is designed to perform controlled expansion of hematopoietic stem cells for bone marrow transplants. The general idea is to cause self-renewal of early stage stem cells and prevent them from differentiating through use of the PluriX™ Bioreactor system. The PluriX™ Bioreactor system creates an artificial physiological environment in which hematopoietic stem cells can grow and reproduce. This system is in direct contrast to standard teflon bags or culture flasks, which cannot promote hematopoietic stem cells self-renewal and prevent their differentiation. In the PluriX™ Bioreactor system, hematopoietic stem cells are influenced by contact with the surrounding environment, made up of stromal cell cultures and substrates. Therefore, by keeping the hematopoietic stem cells in the closed environment of the PluriX™ Bioreactor system, the hematopoietic stem cells maintain their original form, which means that they proliferate without differentiating.

The PluriX™ Bioreactor system enables the production of certain stem cells, such as umbilical cord blood hematopoietic stem cells, for which there might otherwise be insufficient quantities available for many transplants. Having access to a sufficient number of hematopoietic stem cells is essential to successful clinical outcomes. This is particularly the case with umbilical cord blood transplants. The limited quantities of available hematopoietic stem cells in umbilical cord blood and difficulties in expanding the starting volumes to therapeutic quantities have restricted the widespread practice of umbilical cord blood transplants. The PluriX™ Bioreactor system is designed to solve this dilemma by providing the capability to easily and cost-effectively expand umbilical cord blood hematopoietic stem cells to higher quantities for therapeutic treatments.

The PluriX™ Bioreactor System is comprised of several components, including (1) a reservoir, (2) gas mixture, (3) a gas filter, (4) an injection point, (5) a Plug Flow Bioreactor, (6) a flow monitor and a flow valve, (7) a separating container, (8) a container for medium exchange, (9) a peristaltic pump, (10) a sampling point, (11) a container for

medium exchange and (12) an oxygen monitor. The PluriX™ Bioreactor system is designed to be operated with minimal operator activity by a medical or laboratory technician Working with the PluriX™ Bioreactor system is intended to be relatively simple, and therefore, a trained lab technician will be able to operate and monitor between 10 to 20 PluriX™ Bioreactor systems at any one time. In other words, one lab technician will operate 70 to 100 PluriX™ Bioreactor systems per year.

Primary Advantages of PluriX™ Bioreactor System

We believe our core technology, the PluriX™ Bioreactor system, once fully developed, will have the following advantages:

- Our PluriX™ Bioreactor system can be used to expand umbilical cord blood hematopoietic stem cells for use in adults. With the assistance of our PluriX™ Bioreactor system, one portion of umbilical cord blood hematopoietic stem cells can be expanded to quantities enough for a number of transplants. This means that healthy autologus umbilical cord blood hematopoietic stem cells can be taken at the time of birth, expanded into mature hematopoietic stem cells and stored by a cell bank in the instance that it may be needed by that specific patient at a later date. This will eliminate the current practice of transplanting cancerous cells back into the patient.

- Our PluriX™ Bioreactor system can be used for allogenic expansion, i.e. to expand the hematopoietic stem cells from donors other than the patient himself. Allogenic stem cells can also be expanded for use as a transplant source for adults in the instances that enough stem cells are not attainable from a particular donor.

- Our PluriX™ Bioreactor system can also be used for autologus proliferation, i.e. to expand the hematopoietic stem cells taken from the transplant patients themselves. Contrary to any existing available technologies known to us, our PluriX™ Bioreactor system will allow the use of autologus bone marrow transplantation in the case that healthy cells are not clearly attainable from the patient.

- By making the option of expanding hematopoietic stem cells taken from transplant patients themselves available, we believe that costs related to donor searches for bone marrow transplants will be reduced significantly;

- Our PluriX™ Bioreactor system can be used to produce a high number of hematopoietic stem cells, which will result in increased potential for faster, successful engraftment of stem cells in transplant patients;

- We believe that our PluriX™ Bioreactor system will produce by-products that will speed up the recovery time of transplant patients, thereby reducing the number of hospitalization days needed.

Alongside our research process on the PluriX™ Bioreactor system, we have also identified characterization processes of new proteins that are important to the differentiation of stem cells, both within and without patients' bodies. We plan to continue in the cleaning and characterization of these proteins with the intention of making them into commercial products.

Markets for Our Product and Services

There are presently between 40,000 to 50,000 bone marrow transplants performed annually worldwide; approximately 18,000 are performed in the United States and approximately 25,000 are performed in Europe. We have not taken steps to determine the number of bone marrow transplants performed in the Pacific Rim. Of the 40,000 to 50,000 bone marrow transplants performed, only 5,000 are performed on babies and children. Furthermore, most of these 40,000 to 50,000 bone marrow transplants are allogenic transplants, requiring patients to locate donors with compatible hematopoietic stem cells. Taking into account that only one in three patients actually find a compatible donor, the number of potential bone marrow transplants is estimated to exceed 150,000 annually. Based on these statistics, we believe that the existing methods of transplanting human bone marrow have not been perfected and are far from

reaching an ideal level of success.

Presently, the standard bone marrow transplant procedure costs approximately $100,000 per patient. This translates into approximately $5 billion annually that patients and their medical insurers around the world are spending currently for this procedure alone. In addition, to manage the risk of incompatibility between donor and patient stem cells, a separation procedure of the stem cells is frequently also performed at a cost of $70,000. We believe that 15% to 20%, or 15,000 to 20,000 of the patients require this stem cell separation procedure as well, adding a further $700 million to the current spending on bone marrow transplants in the United States. Combining these figures with similar expenditures in Europe and Asia, we estimate the current worldwide spending on bone marrow transplants to exceed $7 billion per year.

We estimate that there are between ten to one hundred cord blood banks in the world, most of them located in the United States. In 2001, they collective cryo-preserved (frozen) and stored cord blood from some 34,000 to 36,000 donors and they project that the annual rate of growth of cord blood preserved will be over 15%. Due to the increased use of umbilical cord blood hematopoietic stem cells in bone marrow transplants, we expect that the number of cord blood banks will also grow significantly around the world. We also expect that, in developed countries, in the near future, umbilical cord blood may be drawn at the time of every birth and stored for later use. We believe that the stem cell expansion services that we will make available through our PluriX™ Bioreactor system, together with proper marketing efforts, will increase the number of umbilical cord blood donors for personal use, i.e., parents storing the umbilical cord blood for their children's future, by more than doubling the existing growth rate. This will also provide a full base of hematopoietic stem cells donor opportunities to patients throughout the world. We project that the global market for the provision of stem cell expansion services can reach approximately $8 billion.

Intellectual Property

Our success will depend in part on our ability, and the ability of our licensors, to obtain patent protection for our products and processes under the License Agreement. Under the License Agreement we have exclusive rights to U.S. patent application number PCT/US00/02688 entitled "Method and Apparatus for Maintenance and Expansion of Hematopoietic Stem Cells and/or Progenitor Cells" which was also filed with the World Intellectual Property Organization under the Patent Cooperation Treaty (PCT) patent number WO-00/46349 for our core technology of the PluriX™ Bioreactor system. Our issued patent presents claims to: (i) certain apparatus for cell culturing, including a bioreactor suitable for culturing human hematopoietic stem cells or hematopoietic progenitors cells; (ii)three dimensional stromal cells based bioreactor. A patent was issued in South Africa in October, 2002, and is due to expire in approximately 2020. In addition, we and our exclusive licensors have filed applications for patents in the United States and equivalent applications in certain other countries claiming other aspects of our products and processes, including a number of U.S. patent applications and corresponding applications in other countries related to various components of the PluriX™ Bioreactor system.

The validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications by us, or our licensors, will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us or our licensors will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or design around any patents that have been or may be issued to us or our licensors. Since patent applications in the United States are maintained in secrecy until patents issue, we also cannot be certain that others did not first file applications for inventions covered by our, and our licensors' pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We rely on the license granted by Weizmann Institute of Science and Technion-Israel Institute of Technology and others for certain patent rights. If we breach the License Agreement or otherwise fail to comply with the License Agreements, or if the License Agreement expires or is otherwise terminated, we may lose our rights in such patent, which would have a material adverse affect on our business, financial condition and results of operations.

Pluristem applied for a U.S. Trademark on the word "PluriX" on June 22, 2003.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. It has not been, but is now our intended policy to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, board of directors, technical review board and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements will provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also will commence to require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements will generally provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of Pluristem. There can be no assurance, however, that all persons who we desire to sign such agreements will sign, or if they do, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

Our success will also depend in part on our ability to commercialize our technology 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 market our technology or maintain our competitive position with respect to our technology. 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. 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 technology 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 and commercialization of our technology.

Research and Development

Foundational Research

For the last five years, Dr. Shai Meretski, a member of the Pluristem team, made the initial strides in the development of our core technology, the PluriX™ Bioreactor system. Research was performed in the laboratory of Dr. Shosh Merchav at the Technion - Israel Institute of Technology's Rappaport Faculty of Medicine. Dr. Meretski worked in close collaboration with Professor. Dov Zipori and Dr. Avinoam Kaduri, both from the Weizmann Institute of Science. Professor Zipori specializes in cultures and stromal cells and Dr. Kaduri specializes in the planning and creation of bioreactors. Special carriers were used in our research and development process. In addition, this foundational research was conducted in joint cooperation with the laboratory of SCID-NOD mice at the Weizmann Institute of Science and with Plumacher Laboratories in Rotterdam. To this end, Plumacher Laboratories allocated a research physician to the project for over two years.

Product Development

For the next three to four years, we intend to operate on the following four major stages, culminating in the launching of our hematopoietic stem cells expansion services:

First Stage - Culture Foundation: At this stage we intend to focus on the capacity characterization of existing two-dimensional stromal cell cultures to support pluripotent hematopoietic stem cells; establishment and preparation of several new PluriX™ Bioreactor systems for laboratory work and long-term growth of our high-density three dimensional stromal cells cultures in the PluriX™ Bioreactor systems.

Second Stage - Co-Culture Development & Optimization: At this stage we intend to focus on the establishment of the PluriX™ Bioreactors containing high-density cell and pluripotent hematopoietic stem cells co-cultures; maintenance of common cells (CD34+38- and CD34+38-CXCR4+) on high-density cell-coated carriers and testing of ex vivo expanded stem cells on mice, monkeys and clinical trials.

Third Stage - Characterization & Protein Analysis: At this stage we intend to focus on the analysis of activity in media conditioned by the high-density cell cultures in the PluriX™ Bioreactor systems; expansion standardization of pluripotent hematopoietic stem cells and hematopoietic progenitors in the PluriX™ Bioreactor system and comparison to expansion in standard stromal cell cultures and analysis of protein content expressed in PluriX™ cell cultures by two-dimensional electrophoresis.

Final Stage - Regulatory Approval: At this stage we intend to prepare and file with the FDA and other relevant health authorities an Investigational New Drug or an Investigational Device Exemption application to initiate human clinical trials designed to demonstrate the safety, efficacy and clinical benefits of selectively expanded stem cell populations from umbilical cord blood.

Employees

Pluristem Ltd., fully owned by Pluristem Life Systems Inc., presently employees six people in R&D and three people in management. In June, 2003, we hired two PhD's, a Quality Assurance expert, a chemical engineer, and four laboratory technicians to oversee the research, lab tests and clinical trials.

Competition

The biotechnology and medical device industries are characterized by rapidly evolving technology and intense competition. Our competitors include major pharmaceutical, medical device, medical products, chemical and specialized biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours. In addition, many biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with ours. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint ventures. We are aware of certain other products manufactured or under development by competitors that are used for the prevention or treatment of certain diseases and health conditions that we have targeted for product development. There can be no assurance that developments by others will not render our technology obsolete or noncompetitive, that we will be able to keep pace with new technological developments or that our technology will be able to supplant established products and methodologies in the therapeutic areas that are targeted by us. The foregoing factors could have a material adverse affect on our business, financial condition and results of operations.

Our competition will be determined in part by the potential indications for which our technology is developed and ultimately approved by regulatory authorities. In addition, the first product to reach the market in a therapeutic or preventive area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the

relative speed with which we, or our potential corporate partners, can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors. Our competitive position will also depend on our ability to attract and retain qualified scientific and other personnel, develop effective proprietary products, develop and implement production and marketing plans, obtain and maintain patent protection and secure adequate capital resources. We expect our technology, if approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability, value and patent position.

We believe we complete with the following larger and more established specialized biotechnology companies that are developing devices and products to be used for the prevention or treatment of certain diseases and health conditions that we have targeted for product development: Aastrom Biosciences, Inc., ViaCell Inc., Gamida-Cell Ltd., Advanced Cell Technology, Inc., BioTransplant Inc., and CellGenix. However, to the best of our knowledge none of these companies have developed a platform that can support expansion of hematopoietic stem cells without promoting their differentiation.

Government Regulations and Supervision

Our research and development activities and the manufacturing and marketing of our technology are subject to the laws and regulations of governmental authorities in the United States and other countries in which our technology will be marketed. Specifically, in the United States, the Food and Drug Administration (the "FDA"), among other activities, regulates new product approvals to establish safety and efficacy of these products. Governments in other countries have similar requirements for testing and marketing.

Regulatory Process in the United States

We may develop our PluriX™ Bioreactor system into a GMP-compliant cell culture system for *ex vivo* human cell production to be sold for therapeutic applications. Therefore, to a certain degree, the manner in which the FDA will regulate our PluriX™ Bioreactor system is uncertain.

The product output of our PluriX™ Bioreactor system is potentially subject to regulation as medical products under the Federal Food, Drug and Cosmetic Act, and as biological products under the Public Health Service Act. Different regulatory requirements may apply to our technology depending on how they are categorized by the FDA under these laws.

The FDA is still in the process of developing its requirements with respect to somatic cell therapy and gene cell therapy products and has issued draft documents concerning the regulation of cellular and tissue-based products. If the FDA adopts the regulatory approach set forth in the draft document, the FDA will require regulatory approval for certain human cellular or tissue based products, including cells produced in the PluriX™ Bioreactor system, through a biologic license application.

The FDA has published regulations which require registration of certain facilities, which may include our future clinics, and is in the process of publishing regulations for the manufacture or manipulation of human cellular or tissue based products which may impact our future clinics.

Regulatory approval of new medical devices and biological products is a lengthy procedure leading from development of a new product through pre-clinical and clinical testing. This process takes a number of years and the expenditure of significant resources. There can be no assurance that our technology will ultimately receive regulatory approval.

Regardless of how our technology is regulated, the Federal Food, Drug, and Cosmetic Act and other Federal statutes and regulations govern or influence the research, testing, manufacture, safety, labelling, storage, record-keeping, approval, distribution, use, reporting, advertising and promotion of such products. Noncompliance with applicable

requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution.

Product Approval

In order to obtain FDA approval of a new medical product, sponsors must generally submit proof of safety and efficacy. In some cases, such proof entails extensive pre-clinical and clinical laboratory tests. The testing, preparation of necessary applications and processing of those applications by the FDA is expensive and may take several years to complete. There can be no assurance that the FDA will act favorably or in a timely manner in reviewing submitted applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals, in turn, which could delay or preclude us from marketing any products we may develop. The FDA may also require post-marketing testing and surveillance of approved products, or place other conditions on the approvals. These requirements could cause it to be more difficult or expensive to sell the products, and could therefore restrict the commercial applications of such products. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. For patented technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have the exclusive right to exploit such technologies.

If human clinical trials of a proposed medical product are required, the manufacturer or distributor of the product will have to file an Investigational Device Exemption or Investigational New Drug submission with the FDA prior to commencing human clinical trials. The submission must be supported by data, typically including the results of pre-clinical and laboratory testing. Following submission of the Investigational Device Exemption or Investigational New Drug, 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 believe our technology, the PluriX™ Bioreactor system, may be classified as Class III medical devices. The FDA categorizes devices into three regulatory classifications subject to varying degrees of regulatory control. In general, Class I devices require compliance with labelling and record keeping regulations, Quality System Regulation, 510(k) pre-market notification, and are subject to other general controls. Class II devices may be subject to additional regulatory controls, including performance standards and other special controls, such as post-market surveillance. Class III devices, which are either invasive or life-sustaining products, or new products never before marketed (for example, non-"substantially equivalent" devices), require clinical testing to demonstrate safety and effectiveness and FDA approval prior to marketing and distribution. The FDA also has the authority to require clinical testing of Class I and Class II devices.

We, and any contract manufacturer, may be required to be registered as a medical device manufacturer with the FDA. These manufacturers will be inspected on a routine basis by the FDA for compliance with the FDA's Quality System Regulations. The FDA's regulations would require that we, and any contract manufacturer, design, manufacture and service products and maintain documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control and service activities. The Medical Device Reporting regulation requires that we provide information to the FDA on deaths or serious injuries alleged to be associated with the use of our devices, as well as product malfunctions that are likely to cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits a company from promoting an approved device for unapproved applications and reviews company labeling for accuracy.

We believe that the cells produced in the PluriX™ Bioreactor system may be regulated by the FDA as a licensed biologic, although there can be no assurance that the FDA will not choose to regulate this product in a different manner. The FDA categorizes human cell or tissue based products as either minimally manipulated or more than minimally manipulated, and has proposed that more than minimally manipulated products be regulated through a

"tiered approach intended to regulate human cellular and tissue based products only to the extent necessary to protect public health." For products which may be regulated as biologics, the FDA requires: (i) preclinical laboratory and animal testing; (ii) submission to the FDA of an Investigational Device Exemption or Investigational Device Exemption New Drug application which must be effective prior to the initiation of human clinical studies; (iii) adequate and well-controlled clinical trials to establish the safety and efficacy of the product for its intended use; (iv) submission to the FDA of a biologic license application; and (v) review and approval of the biologic license application as well as inspections of the manufacturing facility by the FDA prior to commercial marketing of the product.

Pre-clinical testing covers laboratory evaluation of product chemistry and formulation as well as animal studies to assess the safety and efficacy of the product. The results of these tests are submitted to the FDA as part of the Investigational Device Exemption. Following the submission of an Investigational Device Exemption, 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. Clinical trials are typically conducted in three sequential phases. Phase I represents the initial administration of the drug or biologic to a small group of humans, either healthy volunteers or patients, to test for safety and other relevant factors. Phase II involves studies in a small number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range and to gather additional data relating to safety and potential adverse affects. Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, multi-center Phase III studies are initiated to establish safety and efficacy in an expanded patient population and multiple clinical study sites. The FDA reviews both the clinical plans and the results of the trials and may request us to discontinue the trials at any time if there are significant safety issues.

The results of the pre-clinical tests and clinical trials are submitted to the FDA in the form of a biologic license application for marketing approval. The testing and approval process is likely to require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. Additional animal studies or clinical trials may be requested during the FDA review period that may delay marketing approval. After FDA approval for the initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications. The FDA requires that adverse affects be reported to the FDA and may also require post-marketing testing to monitor for adverse affects, which can involve significant expense.

Under current requirements, facilities manufacturing biological products must be licensed. To accomplish this, a biologic license application must be filed with the FDA. The biologic license application describes the facilities, equipment and personnel involved in the manufacturing process. An establishment license is granted on the basis of inspections of the applicant's facilities in which the primary focus is on compliance with regulations and procedures and the ability to consistently manufacture the product in the facility in accordance with the Investigational Device Exemption. If the FDA finds the inspection unsatisfactory, it may decline to approve the biologic license application, resulting in a delay in production of products.

As part of the approval process for human biological products, each manufacturing facility must be registered and inspected by the FDA prior to marketing approval. In addition, state agency inspections and approvals may also be required for a biological product to be shipped out of state.

Regulatory Process in Europe

Our PluriX™ Bioreactor system may be regulated in Europe as a Class I Sterile, Class IIb or Class III medical device, under the authority of the Medical Device Directives being implemented by European Union member countries. These classifications apply to medical laboratory equipment and supplies including, among other products, many devices that are used for the collection and processing of blood for patient therapy.

The Medical Device Directives regulations vest the authority to permit affixing of the CE Mark with various notified bodies. These are private and state organizations which operate under license from the member states of the European Union to certify that appropriate quality assurance standards and compliance procedures are followed by developers and manufacturers of medical device products or, alternatively, that a manufactured medical product meets a more limited set of requirements. Notified bodies are also given the responsibility for determination of the appropriate standards to apply to a medical product. Receipt of permission to affix the CE Mark enables a company to sell a medical device in all European Union member countries. Other registration requirements may also need to be satisfied in certain countries. We have not received permission from a notified body to affix the CE Mark to our PluriX™ Bioreactor system.

Risk Factors

Much of the information included in this current report includes or is based upon estimates, projections or other "forward looking statements". Such forward looking statements include any projections or estimates made by us and our management in connection with our business operations. While these forward-looking statements, and any assumptions upon which they are based, are made in good faith and reflect our current judgment regarding the direction of our business, actual results will almost always vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein.

Such estimates, projections or other "forward looking statements" involve various risks and uncertainties as outlined below. We caution the reader that important factors in some cases have affected and, in the future, could materially affect actual results and cause actual results to differ materially from the results expressed in any such estimates, projections or other "forward looking statements".

Our common shares are considered speculative during the development of our new business operations. Prospective investors should consider carefully the risk factors set out below.

Limited Operating History

Our company has a limited operating history and must be considered in the development stage. Our company's operations will be subject to all the risks inherent in the establishment of a developing enterprise and the uncertainties arising from the absence of a significant operating history. No assurance can be given that we may be able to operate on a profitable basis.

Likelihood of Profit

Our securities must be considered highly speculative, generally because of the nature of our business and the early stage of its development. We are engaged in the business of developing and commercializing a technology and device to expand hematopoietic stem cells outside of the human body without differentiation. Our technology is in the development stage and we have not begun the regulatory approval process for our technology and device. Accordingly, 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 business will be dependent upon successful commercialization of our core technology, the PluriX™ Bioreactor system, which itself is subject to numerous risk factors as set forth herein.

Our inability to complete our product development activities successfully would severely limit our ability to operate or finance operations.

Commercialization of our core technology, the PluriX™ Bioreactor system, will require significant additional research and development as well as substantial clinical trials. We believe that the United States will be the principal market for our technology. We may not be able to successfully complete development of the PluriX™ Bioreactor system, or

successfully market our technology. 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 core technology may not prove to be safe and efficacious in clinical trials, and we may not obtain the intended regulatory approvals for our core technology and the cells produced in such products. Whether or not 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.

Lack of Financial Resources

Our ability to continue develop and, if warranted, commercialize our core technology, the PluriX™ Bioreactor system, will be dependent upon our ability to raise significant additional financing. If we are unable to obtain such financing, we will not be able to fully develop and commercialize our technology. 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, no cash flow from operations and we are dependent for funds on our ability to sell our common shares, primarily on a private placement basis. There can be no assurance that we will be able to obtain financing on that basis in light of factors such as the market demand for our securities, the state of financial markets generally and other relevant factors. The method of financing employed by us to date results in increased dilution to the existing shareholders each time a private placement is conducted.

Failure to obtain and maintain required regulatory approvals would severely limit our ability to commercialize our technology.

We believe that we must obtain the approval of the FDA before commercialization of our technology may commence in the United States, which we believe will be the principal market for our technology. We may also be required to obtain additional approvals from foreign regulatory authorities to continue or increase our sales activities in those jurisdictions. If we cannot demonstrate the safety, reliability and efficacy of our technology, or of the cells produced in our technology, including long-term sustained engraftment, or if one or more patients die or suffer severe complications in future clinical trials, the FDA or other regulatory authorities could delay or withhold regulatory approval of our technology.

Finally, even if we obtain regulatory approval of our technology, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA, other regulatory agencies, and governments in other countries 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.

Even if we obtain regulatory approvals to commericialize our technology, lack of commercial acceptance would impair our business.

Our product development efforts are primarily directed toward obtaining regulatory approval to market the PluriX™ Bioreactor system as an alternative to, or as an improvement for, the bone marrow harvest and peripheral blood progenitor cell stem cell collection methods. These stem cell collection methods have been widely practiced for a number of years, and our technology may not be accepted by the marketplace as readily as these or other competing processes and methodologies. Additionally, our technology 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 technology 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 may become obsolete and our business may suffer.

The market for our technology is very competitive, is subject to rapid technological changes and varies for different individual products. We believe that there are potentially many competitive approaches being pursued in competition to our technology, including some by private companies for which information is difficult to obtain.

Many of our competitors have significantly greater resources, more product candidates and have developed product candidates and processes that directly compete with our technology. Our competitors may have developed, or could in the future develop, new technologies that compete with our technology or even render our technology obsolete. Our technology are designed to improve and automate the processes for producing cells used in therapeutic procedures. Even if we are able to demonstrate improved or equivalent results, researchers and practitioners may not use our technology and we will suffer a competitive disadvantage. As a result, we may be unable to recover the net book value of our inventory. Finally, to the extent that others develop new technologies that address the targeted application for our current technology, our business will suffer.

Dependence on Key Personnel/Employees

We are dependent on our ability to hire and retain highly qualified scientific and management personnel, including our President, Dr. Irit Arbel and the founder and Chief Technology Officer of Pluristem, Ltd., Dr. Shai Meretski. 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.

If our patents and proprietary rights do not provide substantial protection, then our business and competitive position will suffer.

Our success depends in large part on our ability to develop or license and protect proprietary technology. However, patents may not be granted on any of our pending or future patent applications. Also, the scope of our issued patent may not be sufficiently broad to offer meaningful protection. In addition, the patent licensed to us could be successfully challenged, invalidated or circumvented so that our patent rights would not create an effective competitive barrier. Furthermore, we rely on an exclusive, world-wide license relating to the production of human cells granted to us by the Weizmann Institute of Science and Technion-Israel Institute of Technology for certain of our patent rights. If we materially breach such agreement or otherwise fail to materially comply with such agreement, or if such agreement expires or is otherwise terminated by us, we may lose our rights under the patent held by the Weizmann Institute of Science and Technion-Israel Institute of Technology. At the latest, the license will terminate when the patent underlying the license expires. The underlying patents will expire in approximately 2020. 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.

Intellectual property litigation could harm our business.

Our success will also depend in part on our ability to develop commercially viable products without infringing the proprietary rights of others. Although we have not been subject to any filed infringement claims, other patents could exist or could be filed which would prohibit or limit our ability to market our products or maintain our competitive position. In the event of an intellectual property dispute, we may be forced to litigate. Intellectual property litigation would divert management's attention from developing our technology and would force us to incur substantial costs regardless of whether we are successful. An adverse outcome could subject us to significant liabilities to third parties, and force us to curtail or cease the development and commercialization of our technology.

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

We face an inherent business risk of exposure to product liability claims in the event that the use of the PluriX™ Bioreactor system during research and development efforts, including clinical trials, or after commercialization results in adverse affects. As a result, we may incur significant product liability exposure, which could exceed existing insurance coverage. 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 increase our operating loss and affect our financial condition.

"Penny Stock" Rules May Restrict the Market for the Company's Shares

Our shares of common stock are subject to rules promulgated by the Securities and Exchange Commission relating to "penny stocks," which apply to companies whose shares are not traded on a national stock exchange or on the NASDAQ system, trade at less than $5.00 per share, or who do not meet certain other financial requirements specified by the Securities and Exchange Commission. These rules require brokers who sell "penny stocks" to persons other than established customers and "accredited investors" to complete certain documentation, make suitability inquiries of investors, and provide investors with certain information concerning the risks of trading in the such penny stocks. These rules may discourage or restrict the ability of brokers to sell our shares of common stock and may affect the secondary market for our shares of common stock. These rules could also hamper our ability to raise funds in the primary market for our shares of common stock.

Possible Volatility of Share Prices

Our shares of common stock are currently publicly traded on the Over-the-Counter Bulletin Board service of the National Association of Securities Dealers, Inc. The trading price of our shares of common stock has been subject to wide fluctuations. Trading prices of our shares of common stock may fluctuate in response to a number of factors, many of which will be beyond our control. The stock market has generally experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies with no current business operation. There can be no assurance that trading prices and price earnings ratios previously experienced by our shares of common stock will be matched or maintained. These broad market and industry factors may adversely affect the market price of our shares of common stock, regardless of our operating performance.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted. Such litigation, if instituted, could result in substantial costs for us and a diversion of management's attention and resources.

The companyOur Principal has importantResearch and Development Facilities are Located in in Iisrael, which Has Historically Experienced Military and Political Unrest.

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. Any major hostilities involving Israel, or the interruption or curtailment of trade between Israel and its present trading partners, could significantly harm our business, operating results and financial condition.

Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and, since September 2000, involving the Palestinian population, and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel and companies based in Israel. 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, the Company cannot predict whether or in what manner these problems will be resolved. Also, since the end of September 2000, there has been a marked increase in the level of terrorism in Israel, which has significantly damaged both the Israeli economy and levels of foreign and local investment.

In addition, 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 45 and 54 years old, depending upon the nature of their military service.

Indemnification of Directors, Officers and Others

Our by-laws contain provisions with respect to the indemnification of our officers and directors against all expenses (including, without limitation, attorneys' fees, judgments, fines, settlements, and other amounts actually and reasonably incurred in connection with any proceeding arising by reason of the fact that the person is one of our officers or directors) incurred by an officer or director in defending any such proceeding to the maximum extent permitted by Nevada law.

Insofar as indemnification for liabilities arising under the *Securities Act of 1933* may be permitted to directors, officers and controlling persons of our company under Nevada law or otherwise, we have been advised the opinion of the Securities and Exchange Commission is that such indemnification is against public policy as expressed in the *Securities Act of 1933* and is, therefore, unenforceable.

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 judgement and civil liabilities against our officers, directors, experts and agents.

All 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 investors 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.

Future Dilution

Our constating documents authorize the issuance of 1,400,000,000 shares of common stock, each with a par value of $0.00001. In the event that we are required to issue any additional shares or enter into private placements to raise financing through the sale of equity securities, investors' interests in our company will be diluted and investors may suffer dilution in their net book value per share depending on the price at which such securities are sold. If we issue any such additional shares, such issuances also will cause a reduction in the proportionate ownership and voting

power of all other shareholders. Further, any such issuance may result in a change in our control.

Anti-Takeover Provisions

We do not currently have a shareholder rights plan or any anti-takeover provisions in our By-laws. Without any anti-takeover provisions, there is no deterrent for a take-over of our company, which may result in a change in our management and directors.

Government Regulation/Administrative Practices

There is no assurance that the laws, regulations, policies or current administrative practices of any government body, organization or regulatory agency in the United States or any other jurisdiction, will not be changed, applied or interpreted in a manner which will fundamentally alter the ability of our company to carry on our business.

The actions, policies or regulations, or changes thereto, of any government body or regulatory agency, or other special interest groups, may have a detrimental effect the Company. Any or all of these situations may have a negative impact on one or more of the Company's ability to operate and/or its profitably.

PLAN OF OPERATIONS

Upon completion of development of our products and upon regulatory approval, Pluristem will attempt to work closely with both transplant centers and cord blood banks. In each case, we intend to supply umbilical cord blood hematopoietic stem cells expansion services upon demand. Patients will receive full treatment in the transplant clinics. During this time, the transplant clinics perform searches of umbilical cord blood hematopoietic stem cells donors among the other clinics and the cord blood banks. Once a compatible donor has been found, the hematopoietic stem cells will be transferred to our clinics for expansion.

We intend to set up stem cell expansion clinics in close proximity to the transplant clinics and cord blood banks. It is expected that the initial clinics will be located in the United States and, within two years of establishing the initial clinics, we will set up additional clinics in Europe while expanding the services in the United States. Once we have established full operations, we expect that each of our clinics will have lab technicians capable of processing over 4,000 stem cell expansions per year. We believe that achieving a large market size will require the establishment of several of these clinics over the years following regulatory approvals.

As cord blood hematopoietic stem cells are becoming more popular in their use for bone marrow transplants, in spite of their current low success rate, cord blood banks are quickly taking hold around the world. Accordingly, we perceive great importance in working closely with cord blood banks as well as with the treatment clinics. Cord blood banks perform three primary functions:

1. Cord Blood Collection Service - Collect cord blood from donors, i.e. at time of birth, at the maternity units of hospitals;
2. Storing Service - The umbilical cord blood is processed and frozen until it is needed by a patient. The average cell loss after processing in most cord blood banks is 25%-50%, meaning that even less umbilical cord blood is available for expansion purposes.
3. Donor Search/Distribution - Working closely with transplant clinics, cord blood banks provide detailed donor searches to supply the cord blood to transplant patients.

Cord blood banks are presently limited in their capabilities, making our process a potentially critical link in the bone marrow process. While cord blood banks collect and store umbilical cord blood from patients, they have no expansion technologies available and the collected umbilical cord blood contains 10%-50% less cells after thawing. Currently , supply of cord blood is limited to pediatric bone marrow transplants.

We will make further marketing efforts with cord blood banks in order to promote our cord blood hematopoietic stem cells expansion services through our core technology, the PluriX™ Bioreactor system. We will also join in cord blood banks' effort to promote cord blood storage services to young couples and families, wishing to ensure the future health of their babies and children.

In order to establish our company in the hematopoietic stem cells expansion industry, we intend to align ourselves with one or more major suppliers and service providers to the cord blood banks and transplant clinics. This will offer us the ability to make a cost effective entry to the market in a timely fashion. We will begin identifying potential strategic partners towards the end of 2003.

Estimated Expenses:

The estimate expenses referenced herein are in accordance with the business plan. As the technology is still in the development stage, it can be expected that there will be changes in some budgetary items.

- Management Compensation Expenses **-** Our management team will be made up of a Chief Executive Officer, a Chief Financial Officer and a Chief Technology Officer. We estimate that our management compensation expenses for the next fiscal year to be the aggregate amount of $306,000.

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Research and Development Expenses **-** Our research and development process will require us to employ three PhD's, a Quality Assurance expert, a chemical engineer, and four laboratory technicians to oversee the research, lab tests and clinical trials. We will also be required to purchase stem cells from other sources. We will perform tests of our technology on laboratory animals and following with clinical trials. We estimate our research and development expenses for the next fiscal year to be the aggregate amount of $1,045,000.

- Legal Expense **-** We intend to take a very aggressive approach to protecting our intellectual property. We expect that we will incur significant legal expenses to prepare and file a number of patent applications over the next three year period, as new discoveries are made in our research and development process. Furthermore, as a publicly traded company, we expect the incur certain legal expenses to comply with our important reporting responsibilities. We estimate our legal expenses for the next fiscal year to be the aggregate amount of $227,000.

- Business Development and Travel Expenses **-** We will begin business development early on, in order to ensure a rapid and successful entry into the cell expansion market. We estimate our business development and travel expenses for the next fiscal year to be the aggregate amount of $180,000.

Additional costs will be incurred through normal general and administrative expenses such as rent, office supplies, etc. There are no expected revenues from operations in the next 3 years.

Capital Expenditures - Research and Development Facilities:

Pluristem has equipped its laboratory with quality, relatively recent equipment at one-fifth of its new cost. The equipment was purchased from a biotech company that closed its operations shortly after setting up its facilities. It is important to note that a large proportion of the equipment was unused by the other company. Therefore, capital expenditures will be reasonable over the next three years. We estimate our capital expenditure in setting our Research and Development Facilities for the next fiscal year to be the aggregate amount of $167,000.

DESCRIPTION OF PROPERTY

Pluristem has 5,400 square feet of laboratory and office space with three clean rooms and specialized equipment such as a high-level fluorescent microscope.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Principal Stockholders

The following table sets forth, as of June 23, 2003, certain information with respect to the beneficial ownership of our common stock by each stockholder known by us to be the beneficial owner of more than 5% of our common stock, as well as by each of our current directors and executive officers. Each person has sole voting and investment power with respect to the shares of common stock, except as otherwise indicated. Beneficial ownership consists of a direct interest in the shares of common stock, except as otherwise indicated.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership(1)	Percentage of Class(1)
Harvey M. J. Lawson 464 Sommerset Street North Vancouver, BC V7N 1G3	1,064,000 common shares	4.87%
A.R.Y Holdings Ltd. *(2)* *Raul Valenberg st. no. 38* *Haifa, Israel*	4,802,000 common shares	21.99%
Ankor L.L.C. *(3)* *Shlonski St. no. 27* *Haifa, Israel 34987*	1,834,000 common shares	8.40%
Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership(1)	Percentage of Class(1)
Directors and Executive Officers as a Group	5,866,000 common shares	26.86%

(1) Based on 21,833,000 shares of common stock issued and outstanding as of June 23, 2003. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable, or exercisable within 60 days, are deemed outstanding for purposes of computing the percentage ownership of the person holding such option or warrants, but are not deemed outstanding for purposes of computing the percentage ownership of any other person

(2) A.R.Y. Holdings Ltd. entered into an agreement to purchase 4,802,000 shares of our common stock from Emmanuel Aligizakis and Harvey M. J. Lawson and the agreement provided for the transfer of 4,802,000 shares of our common stock to A.R.Y. Holdings Ltd. from Emmanuel Aligizakis and Harvey M.J. Lawson within 60 days of the date of this current report. A.R.Y. Holdings Ltd. is owned and controlled by Dr. Shai Meretski, who is the Chief Technology Officer of our subsidiary, Pluristem, Ltd.

(3) Ankor L.L.C. entered into an agreement to purchase 1,834,000 shares of our common stock from Emmanuel Aligizakis and the agreement provided for the transfer of 1,834,000 shares of our common stock to Ankor L.L.C. from Emmanuel Aligizakis within 60 days of the date of this current report. Ankor L.L.C. is owned and controlled by Dr. Alexander Korat.

DIRECTORS AND EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

As at June 23, 2003, our directors and executive officers, their ages, positions held, and duration of such, are as follows:

Name	Position Held with our Company	Age	Date First Elected or Appointed
Dr. Irit Arbel	President, Chief Executive Officer and Director	43	May 30, 2003
Harvey M.J. Lawson	Secretary, Treasurer and Director	54	Director and Treasurer since May 11, 2001 Secretary since August 12, 2002
Meir Segev	Director	50	March 18, 2003

Business Experience

The following is a brief account of the education and business experience during at least the past five years of each director, executive officer and key employee, indicating the principal occupation during that period, and the name and principal business of the organization in which such occupation and employment were carried out.

Dr. Irit Arbel

Dr. Irit Arbel was recently appointed as our Chief Executive Officer and a director of our company. Dr. Arbel earned her Post Doctorate degree in 1997 in Neurobiology, after performing research in the area of Multiple Sclerosis. Following years of research in the fields of Alzheimer disease, immunology and osteoporosis with numerous publications, Dr. Arbel acquired a wealth of managerial experience through her position as Israeli Sales Manager of Merck, Sharp & Dohme (MSD), a leading pharmaceutical company, from 1998 to 2002. From 1995 to 1997, Dr. Arbel served as the head of research for Hadassa - Ein Karem Hospital in Jerusalem, Israel. Dr Arbel specialized in the use of pharmaceuticals for neurology, ophthalmology and dermatology treatments. Dr. Arbel also holds a Chemical Engineering degree from the Technion, Israel Institute of Technology.

Harvey M.J.

Lawson

Mr. Lawson has been our Treasurer and a member of our board of directors since inception. He became our Corporate Secretary on August 11, 2002. Mr. Lawson has devoted approximately 5% of his professional time to our business and intends to continue to devote this amount of time in the future. From 2001 to present, Mr. Lawson served as the Vice President of Strategic Planning for Golden Fortune Investment Ltd. Golden Fortune Investment Ltd. is a public company listed on the Canadian Venture Exchange involved in resource exploration, and in particular diamond exploration, in Canada. From 2000 to present, Mr. Lawson served as the Corporate Secretary and a director of Litewave Corporation. Litewave Corporation s a public company quoted on the OTC Bulletin Board involved in the development of a satellite/cellular based tracking and system-control device for refrigerated containers. From 1998 to 2001, Mr. Lawson served as the Chief Financial Officer, Corporate Secretary and a director of Ameridian Ventures Inc. Ameridian Ventures Inc. is public company listed on the Canadian Venture Exchange which is involved in copper mining and milling in Chile. In 1999, Mr. Lawson was the Corporate Secretary and a director of Habanero Resources Inc. Habanero Resources Inc. is a public company listed on the Canadian Venture Exchange involved in oil and gas exploration in California. From 1998 to 1999, Mr. Lawson served as a Vice President and a director of SRR Mercantile. SRR Mercantile is a public company listed on the Canadian Venture Exchange involved in mining and procurement of sapphires in Madagascar.

Meir Segev

Meir Segev was appointed as a director of the Company on March 18, 2003. Mr. Segev graduated from University of Haifa and received his Bachelor of Arts degree in political science in 1997. From 1997 to 2002, Mr. Segev served as the Headquarters Division Head of Shabak, the Israel Security Agency. He was primarily responsible for the management and strategic planning of resources and budget for the entire Headquarters Division of Shabak.

Committees of the Board

We do not have an audit or compensation committee at this time. Our entire board of directors will operate as the audit committee until such time when an audit committee is appointed.

Family Relationships

There are no family relationships between any of our directors or executive officers.

Involvement in Certain Legal Proceedings

Other than as discussed below, none of our directors, executive officers, promoters or control persons have been involved in any of the following events during the past five years:

1. any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offences);

3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; or

4. being found by a court of competent jurisdiction (in a civil action), the Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities

law, and the judgment has not been reversed, suspended, or vacated.

EXECUTIVE COMPENSATION

The following table summarizes the compensation of Harvey M.J. Lawson, the former Chief Executive Officer and a director of our company, during the period from incorporation (May 11, 2001) to the end of fiscal year ended June 30, 2002. No other officers or directors received annual compensation in excess of $100,000 during the most recently completed fiscal year.

		Annual Compensation			Long Term Compensation		Pay-outs
Name and Principal Position	Year	Salary	Bonus	Other Annual Compen-sation	Securities Under Options/ SAR's Granted	Restricted Shares or Restricted Share Units	LTIP Pay-outs
Harvey M.J. Lawson Former Chief Executive Officer & Current Director	2002 2001(1)	Nil Nil	$Nil $Nil	Nil Nil	Nil Nil	Nil Nil	Nil Nil

(1)

Incorporated May 11, 2001

Employment/Consulting Agreements

There are no written employment or consulting agreements between the company and any of our directors and executive officers. We have an unwritten agreement with Dr. Irit Arbel whereby the compensation committee will decide on her annual gross salary.

Arrangements and plans to provide pension, retirement or similar benefits for directors or executive officers will be decided upon by the compensation committee. We do not have any material bonus or profit sharing plans pursuant to which cash or non-cash compensation is or may be paid to our directors or executive officers.

Stock Option Plan

There are no stock option plans in favor of any officers, directors, consultants or employees of our company. However, we plan to issue stock options to our directors, officers and employees in the near future.

Stock Options/SAR Grants

There were no grants of stock options or stock appreciation rights to any officers, directors, consultants or employees of our company during the fiscal year ended June 30, 2002.

Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Values

The following table sets forth, for Dr. Irit Arbel, the Chief Executive Officer and a director of our company, stock options exercised during fiscal 2002 and the fiscal year-end value of unexercised options:

Name	Shares Acquired on Exercise (#)	Value Realized ($)	Number of Securities Underlying Unexercised Options/SARs at June 30, 2002 Exercisable/ Unexercisable	Value of Unexercised In-the-Money Options at June 30, 2002 Exercisable/ Unexercisable
Dr. Irit Arbel President	Nil	Nil	Nil	Nil

Directors Compensation

We reimburse our directors for expenses incurred in connection with attending board meetings but did not pay director's fees or other cash compensation for services rendered as a director in the year ended June 30, 2002.

We have no present formal plan for compensating our directors for their service in their capacity as directors, although in the future, such directors are expected to receive compensation and options to purchase shares of common stock as awarded by our board of directors or (as to future options) a compensation committee which may be established in the future. Directors are entitled to reimbursement for reasonable travel and other out-of-pocket expenses incurred in connection with attendance at meetings of our board of directors. The board of directors may award special remuneration to any director undertaking any special services on behalf of our company other than services ordinarily required of a director. Other than indicated in this annual report, no director received and/or accrued any compensation for his or her services as a director, including committee participation and/or special assignments.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Except as otherwise indicated below, we have not been a party to any transaction, proposed transaction, or series of transactions in which the amount involved exceeds $60,000, and in which, to its knowledge, any of its directors, officers, five percent beneficial security holder, or any member of the immediate family of the foregoing persons has had or will have a direct or indirect material interest.

Item 7. Financial Statements and Exhibits.

(a) Financial Statements

It is not practicable to provide financial statements of the acquired company prepared in accordance with the regulations on the date hereof. Accordingly, the required financial statements will be filed as an amendment to this Current Report on Form 8-K as soon as practicable, but not later than August 22, 2003 (60 days after this Current Report on Form 8-K must be filed).

(b) Pro Forma Financial Information

It is not practicable to provide the required pro forma financial statements on the date hereof. Accordingly, the pro forma financial statements will be filed as an amendment to this Current Report on Form 8-K as soon as practicable, but not later than August 22, 2003 (60 days after this Current Report on Form 8-K must be filed).

(c) Exhibits

Copies of the following documents are included as exhibits to this report pursuant to Item 601 of Regulation S-B.

SEC Ref. No. Title of Document

(2) Plan of acquisition, reorganization, arrangement, liquidation, or succession

2.1 Share Purchase Agreement between AI Software, Inc. and Abramovich Trust Company Ltd. dated June 10, 2003.

(3) Articles of Incorporation, By-laws

3.1 Articles of Incorporation (incorporated by reference from our Form SB-2 Registration Statement, filed September 10, 2001).

3.2 Bylaws (incorporated by reference from our Form SB-2 Registration Statement, filed September 10, 2001).

3.3 Certificate of Forward Split, dated March 27, 2003 (incorporated by reference from our Form 8-K Current Report, filed April 8, 2003)

(4) Subsidiaries

Pluristem, Ltd.

(10) License Agreement

10.1 A.I. Software signed an agreement with Weitzman and the Technion to acquire patent-pending technology in its early stages that expands stem cells from umbilical cord blood without differentiation, possibly allowing better results in cord blood transplants in adults (incorporated by reference from our Form 8-K Current Report, filed May 6, 2003).

SIGNATURES

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

AI SOFTWARE, INC.

Date: June 25, 2003

/s/ Irit Arbel

Dr. Irit Arbel, Chief Executive Officer & Director