BIOTIME INC
Form S-3/A
December 03, 2010
As filed with the Securities and Exchange Commission on December 3, 2010

Registration No. 333-167822

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT No. 2
to
FORM S-3

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

BIOTIME, INC.
(Exact name of Registrant as specified in charter)

California	94-3127919
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1301 Harbor Bay Parkway, Suite 100 Alameda, California 94502 (510) 521-3390	Judith Segall, Vice-President and Secretary BioTime, Inc. 1301 Harbor Bay Parkway, Suite 100 Alameda, California 94502 (510) 521-3390
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)	(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including all communications sent to the agent for service, should be sent to:
RICHARD S. SOROKO, ESQ.
Thompson, Welch, Soroko & Gilbert LLP
201 Tamal Vista Blvd.
Corte Madera, California 94925
Tel. (415) 927-5200

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 of the Securities Act of 1933, other than securities offered only in connection with dividend or interest

reinvestment plans, check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Securities Exchange Act of 1934. (Check one):

Large accelerated filer ¨		Accelerated filer o
Non-accelerated filer ¨	(Do not check if a smaller reporting company)	Smaller reporting company x

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its Effective Date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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PROSPECTUS

BIOTIME, INC.

300,000 Warrants
1,383,400 Common Shares
300,000 Common Shares Issuable Upon Exercise of Warrants

This prospectus relates to 1,383,400 common shares and 300,000 common share purchase warrants, and the common shares that may be issued upon the exercise of the warrants, held by the selling security holders named in this prospectus who acquired the common shares and warrants from us in connection with our acquisition of ES Cell International Pte Ltd. We will receive the exercise price of the warrants when the warrants are exercised. However, all of the net proceeds from the sale of the common shares and warrants, and any common shares issued upon the exercise of the warrants, by the selling security holders will belong to the selling security holders and not to us.

The selling security holders may hold their common shares and warrants, and any common shares issued upon the exercise of their warrants, for investment purposes, or they may sell their common shares, including any common shares acquired through the exercise their warrants, from time to time on the NYSE Amex at prevailing market prices, or at prices related to the prevailing market price, or in privately negotiated transactions. The selling security holders may also sell some or all of their warrants in privately negotiated transactions.

The common shares are quoted on the NYSE Amex under the symbol BTX. The closing price of the common shares on the NYSE Amex on November 29, 2010 was $7.87.

These securities involve a high degree of risk and should be purchased only by persons who can afford the loss of their entire investment. See ‘‘Risk Factors’’ on page 11.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is December __, 2010

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PROSPECTUS SUMMARY

The following summary explains only some of the information in this prospectus. More detailed information and financial statements appear elsewhere in this prospectus. Statements contained in this prospectus that are not historical facts may constitute forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those discussed. Words such as “expects,” “may,” “will,” “anticipates,” “intends,” “pla “believes,” “seeks,” “estimates,” and similar expressions identify forward-looking statements. See “Risk Factors.”

BioTime, Inc.

Overview

We are a biotechnology company engaged in two areas of biomedical research and product development. The first products we developed consist of blood plasma volume expanders and related technology for use in surgery, emergency trauma treatment, and other applications. Our lead blood plasma expander product, Hextend®, is a physiologically balanced intravenous solution used in the treatment of hypovolemia. Hypovolemia is a condition caused by low blood volume, often from blood loss during surgery or from injury. Hextend maintains circulatory system fluid volume and blood pressure and keeps vital organs perfused during surgery and trauma care.

We are now primarily focusing our business on regenerative medicine. Regenerative medicine refers to therapies based on human embryonic stem (“hES”) cell and induced pluripotent stem (“iPS”) cell technology designed to rebuild cell and tissue function lost due to degenerative disease or injury. These novel stem cells provide a means of manufacturing every cell type in the human body and therefore show considerable promise for the development of a number of new therapeutic products.

The initial focus of our efforts in the regenerative medicine field has been the development and sale of advanced human stem cell products and technology that can be used by researchers at universities and other institutions, by companies in the bioscience and biopharmaceutical industries, and by other companies that provide research products to companies in those industries. Research-only products generally can be marketed without approval by regulatory agencies such as the United States Food and Drug Administration (“FDA”), and are therefore relatively near-term business opportunities when compared to therapeutic products. These products are currently being marketed through our subsidiaries, Embryome Sciences, Inc. (“Embryome Sciences”), BioTime Asia, Limited (“BioTime Asia”), and our recently acquired subsidiary, ES Cell International Pte Ltd (“ESI”).

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We acquired ES on May 3, 2010. Established in 2000, ESI has been at the forefront of advances in hES technology, being one of the earliest distributors of hES cell lines to the research community. ESI has also produced six clinical-grade human embryonic stem cell lines that were derived following principles of current Good Manufacturing Practice ("cGMP") and currently offers them for potential use in therapeutic product development.

On October 18, 2010, we completed the acquisition of 104,027 ordinary shares of Cell Cure Neurosciences Ltd. ("Cell Cure"), and as a result of that acquisition we now own, directly or through ESI, approximately 53.6% of the outstanding Cell Cure ordinary shares. Cell Cure is an Israel-based biotechnology company engaged in the research and development of stem cell-based therapies for retinal and neurological disorders, including the development of retinal pigment epithelial cells for the treatment of macular degeneration, and treatments for multiple sclerosis and Parkinson's using hES and iPS cells.

Human embryonic stem cell technology is approximately 10 years old and evolving rapidly. As a result, we cannot accurately forecast the amount of revenue that the new products we offer might generate.

Our principal office is located at 1301 Harbor Bay Parkway, Suite 100, Alameda, California 94502. Our telephone number is (510) 521-3390.

Hextend ® and PentaLyte ® are registered trademarks of BioTime, Inc., and ESpan™, ReCyte™, PureStem™ and Espy™ are trademarks of Embryome Sciences, Inc. ACTCellerate™ is a trademark licensed to Embryome Sciences, Inc. by Advanced Cell Technology, Inc.

Stem Cells and Products for Regenerative Medicine Research

We are developing products and technology for use in the emerging field of regenerative medicine. Regenerative medicine refers to therapies based on hES cell and iPS cell technology. Because these cells have the ability to transform into all of the cells of the human body (a property called pluripotency), they may provide a means of producing a host of new products of interest to medical researchers. For example, it may be possible to use hES and iPS cells to develop new cell lines designed to rebuild cell and tissue function lost due to degenerative disease or injury, and new cell lines for basic research and discovery of new drugs. Since embryonic stem cells can now be derived in a noncontroversial manner, including through the use of iPS technology, they are increasingly likely to be utilized in a wide array of future research programs in the attempt to restore the function of organs and tissues damaged by degenerative diseases such as heart failure, stroke, Parkinson's disease, macular degeneration, and diabetes, as well as many others.

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In March 2010, we announced the publication of a scientific paper titled “Spontaneous Reversal of Developmental Aging in Normal Human Cells Following Transcriptional Reprogramming,” which was published in the peer-reviewed journal Regenerative Medicine. The paper explains the use of iPS technology to reverse the developmental aging of normal human cells. Using precise genetic modifications, normal human cells were induced to reverse both the “clock” of differentiation (the process by which an embryonic stem cell becomes the many specialized differentiated cell types of the body), and the “clock” of cellular aging (telomere length). As a result, aged differentiated cells became young stem cells capable of regeneration. These findings may have significant implications for the development of new classes of cell-based therapies targeting age-related degenerative disease.

On April 29, 2009, the California Institute for Regeneration Medicine (“CIRM”) awarded us a $4,721,706 grant for a stem cell research project related to our ACTCellerate™ embryonic stem cell technology. Our grant project is titled “Addressing the Cell Purity and Identity Bottleneck through Generation and Expansion of Clonal Human Embryonic Progenitor Cell Lines.” In our CIRM-funded research project we will work with human embryonic progenitor cells (“hEPCs”) generated using our ACTCellerate™ technology. These hEPCs are intermediate in the developmental process between embryonic stem cells and fully differentiated cells. The hEPCs may possess the ability to become a wide array of cell types with potential applications in research, drug discovery, and human regenerative stem cell therapy. The hEPCs are relatively easy to manufacture on a large scale and in a purified state, which may make it advantageous to work with these cells compared to the direct use of hES cells. We will work on identifying antibodies and other cell purification reagents that may be useful in the production of hEPCs that can be used to develop pure therapeutic cells such as nerve, blood vessel, heart muscle, and cartilage, as well as other cell types.

On November 2, 2010, we received notification of three grant awards totaling approximately $733,000 under the U.S. Government's Qualifying Therapeutic Discovery Project ("QTDP") program. On November 30, 2010 we received $476,724 from the QTDP program which is the 2009 portion of the grant award. The balance of the award (the 2010 portion) is scheduled to be received in the first quarter of 2011. The QTDP program was part of the Patient Protection and Affordable Care Act signed into law on March 23, 2010. The QTDP was created by Congress to support investment in qualified biomedical projects that "show potential to develop new therapies, address unmet medical needs, and reduce the long-term growth of healthcare costs." A qualifying therapeutic discovery project is one designed to diagnose, treat or prevent diseases or conditions by conducting preclinical studies or clinical trials or carrying out research protocols for the purpose of securing approval from the Food and Drug Administration. The grants awarded to us were for the maximum amount allowed for three of our programs: our orthopedic product development focusing on novel cell progenitors of cartilage, which is being conducted through our subsidiary OrthoCyte Corporation; our ACTCellerateTM platform for generating embryonic progenitor cells, and our ReCyteTM iPS cell technology program.

We have also developed a new technology that we call PureStemTM that we plan to use to expand our product offerings. PureStemTM technology utilizes the expression of exogenous transcriptional regulators that control the differentiation of hES and iPS cells, and may potentially provide many of the human cell types needed in regenerative medicine. We are seeking patent protection for the PureStemTM technology.

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In addition to acquiring and developing hES cell, iPS cell, and hEPC technology, we have already commenced marketing our first stem cell products for research use through our subsidiaries, Embryome Sciences and BioTime Asia. We are presently offering for sale 36 novel ACTCellerate™ hEPC lines and optimized ESpan™ growth media for the in vitro propagation of those hEPC lines. During December 2010, Embryome Sciences will add a group of new products to its product line. The new products will include 31 new human embryonic progenitor cell lines, associated cell culture media, 53 diverse extracellular matrices, and 62 diverse extracts from conditioned media, all of which will be offered for research use only. Additional information about these new products will be found at www.embryome.com beginning with product launch.

Embryome Sciences has entered into an agreement under which Millipore Corporation became a worldwide distributor of ACTCellerate™ hEPC lines. Millipore's initial offering of Embryome Sciences' products consists of six novel hEPC lines and optimized ESpan™ growth media for the in vitro propagation of each hEPC line. The companies anticipate jointly launching 29 additional hEPC lines and associated ESpan™ growth media within the coming 12 months. The Embryome Sciences products distributed by Millipore may also be purchased directly from Embryome Sciences at Embryome.com.

Embryome Sciences is also developing a relational database that will permit researchers to chart the cell lineages of human development, the genes expressed in those cell types, and antigens present on the cell surface of those cells that can be used in purification. This database will provide the first detailed map of the embryome and will aid researchers in navigating the complexities of human development and in identifying the many hundreds of cell types coming from embryonic stem cells. Our embryome map data base is now available at our website, Embryome.com.

Embryome Sciences also plans to offer for sale an array of hES cell lines carrying inherited genetic diseases such as cystic fibrosis and muscular dystrophy. Study of these cell lines will enable researchers to better understand the mechanisms involved in causing the disease states, which may in turn expedite the search for potential treatments. We intend to offer these hES cell lines for sale online at Embryome.com. Additional new products that we have targeted for development are ESpy™ cell lines, which will be derivatives of hES cells and will emit beacons of light. The ability of the ESpy cells to emit light will allow researchers to track the location and distribution of the cells in both in vitro and in vivo studies.

Embryome Sciences also plans to bring to market other new stem cell growth and differentiation factors that will permit researchers to manufacture specific cell types from hES cells, and purification tools useful to researchers in quality control of products for regenerative medicine. As new products are developed, they will become available for purchase on Embryome.com.

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Our initial efforts to develop therapeutic stem cell products are being conducted through four subsidiaries: BioTime Asia, OncoCyte, OrthoCyte, and Cell Cure. We organized BioTime Asia for the purpose of clinically developing and marketing therapeutic stem cell products in the People's Republic of China, and marketing stem cell research products in China and other countries in Asia. BioTime Asia will initially seek to develop the therapeutic products for the treatment of ophthalmologic, skin, musculo-skeletal system, and hematologic diseases, including the targeting of genetically modified stem cells to tumors as a novel means of treating currently incurable forms of cancer.

We have engaged the services of Dr. Daopei Lu to aid BioTime Asia in arranging and managing clinical trials of therapeutic stem cell products. Dr. Lu is a world-renowned hematologist and expert in the field of hematopoietic stem cell transplants who pioneered the first successful syngeneic bone marrow stem cell transplant in the People's Republic of China to treat aplastic anemia and the first allogeneic peripheral blood stem cell transplant to treat acute leukemia. Nanshan Memorial Medical Institute Limited ("NMMI"), a private Hong Kong company, has entered into an agreement with us under which NMMI has become a minority shareholder in BioTime Asia and will provide BioTime Asia with its initial laboratory facilities and an agreed number of research personnel, and will arrange financing for clinical trials.

We organized OncoCyte for the purpose of developing novel therapeutics for the treatment of cancer based on stem cell technology. We and Embryome Sciences will license certain technology to OncoCyte restricted to the field of cell-based cancer therapies, including early patent filings on targeting stem cells to malignant tumors. OncoCyte's new therapeutic strategy and goal will be to utilize human embryonic stem cell technology to create genetically modified stem cells capable of homing to specific malignant tumors while carrying genes that can cause the destruction of the cancer cells.

We recently organized a new subsidiary, OrthoCyte, for the purpose of developing novel therapeutics based on stem cell technology for the treatment of injuries and disorders affecting the musculoskeletal system, including therapeutics that would regenerate bone, cartilage, tendons, and ligaments. BioTime may transfer or license certain patents and technology to OrthoCyte for use in the field of orthopedic therapies. OrthoCyte will initially work with ACTCellerateTM hEPC lines that show large concentrations of genetic markers associated with the production of cartilage.

Our acquisition of ESI will allow us to use ESI's clinical-grade hES cell lines with our ACTCellerateTM hES technologies and ReCyteTM iPS technologies that allow the derivation of hEPC lines with high levels of purity and scalability. Our goal will be to generate clonal clinical-grade hEPC lines for potential use in research products and therapeutic products with a level of purity and quality unsurpassed in the industry.

Under an agreement with CIRM, we will make five of the ESI cell lines available to California based researchers and CIRM grant recipients. Initially we will provide research-grade cell lines, and by November 23, 2011 we will also make available GMP-compliant grade cell lines along with certain documentation and genomic DNA sequence information. Although no royalties will be payable to us by researchers who acquire the cell lines for research use, researchers that desire to use the GMP-compliant cell lines for therapeutic or diagnostic products or for other commercial purposes may do so only after signing commercialization agreements acceptable to us and entitling us to receive royalties on net sales not to exceed 2% of net sales, reducible to 1.5% if the researcher must pay any other royalties in connection with the resulting product commercialization.

We believe that access to our GMP-compliant cell lines may help CIRM-funded researchers accelerate their work in a wide array of new cell-based therapies and drugs, and more quickly translate the research into products to treat diseases. We may benefit, through a royalty-bearing license, from future commercial revenues from any new products developed from our cell lines. The publication of the research results using our cell lines may also benefit our own work to better understand the characteristics of the cell lines when used to manufacture human therapeutics.

We also have an investment in Cell Cure, an Israel-based biotechnology company focused on developing stem cell-based therapies for retinal and neurological disorders, including the development of retinal pigment epithelial cells for the treatment of macular degeneration, and treatments for multiple sclerosis and Parkinson's. Cell Cure's lead product under development is OpRegen,TM a proprietary formulation of retinal cells designed by Cell Cure to provide a long-term therapy for age-related macular degeneration, the leading cause of blindness in the aging population. In October 2010, Cell Cure entered into a Research and Exclusive License Option Agreement with Teva Pharmaceutical Industries, Ltd. under which Cell Cure granted Teva an option to obtain an exclusive world-wide license to use certain patents and technology to complete the clinical development of, and to manufacture, distribute and sell Cell Cure's lead product, OpRegen™ and a related product OpRegen-Plus™ that is in an earlier stage of development than OpRegen™. Cell Cure's research and development is conducted at Hadassah University Hospital, through research and consulting agreements with Hadasit Medical Research Services and Development Ltd.

There is no assurance that we or any of our subsidiaries will be successful in developing any new technology or stem cell products, or that any technology or products that they may develop will be proven safe and effective in treating cancer or other diseases in humans, or will be successfully commercialized. Our potential therapeutic products are at a very early stage of preclinical development. Before any clinical trials can be conducted by us or any of our subsidiaries, the company seeking to conduct the trials would have to compile sufficient laboratory test data substantiating the characteristics and purity of the stem cells, conduct animal studies, and then obtain all necessary regulatory and clinical trial site approvals, and assemble a team of physicians and statisticians for the trials.

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Plasma Volume Expander Products

We develop blood plasma volume expanders, blood replacement solutions for hypothermic (low temperature) surgery, organ preservation solutions, and technology for use in surgery, emergency trauma treatment, and other applications. Our first product, Hextend®, is a physiologically balanced blood plasma volume expander used for the treatment of hypovolemia. Hypovolemia is a condition caused by low blood volume, often from blood loss during surgery or from injury. Hextend maintains circulatory system fluid volume and blood pressure and helps sustain vital organs during surgery. Hextend, approved for use in major surgery, is the only blood plasma volume expander that contains lactate, multiple electrolytes, glucose, and a medically approved form of starch called hetastarch. Hextend is sterile, so its use avoids the risk of infection. Health insurance reimbursements and HMO coverage now include the cost of Hextend used in surgical procedures.

Hextend has become the standard plasma volume expander at a number of prominent teaching hospitals and leading medical centers, and is part of the United States Armed Forces Tactical Combat Casualty Care protocol. We believe that as Hextend use proliferates within leading U.S. hospitals, other smaller hospitals will follow their lead, contributing to sales growth.

We are also developing another blood volume replacement product, PentaLyte. It, like Hextend, has been formulated to maintain the patient's tissue and organ function by sustaining the patient's fluid volume and physiological balance. We have completed a Phase II clinical trial of PentaLyte in which PentaLyte was used to treat hypovolemia in cardiac surgery. Our ability to commence and complete additional clinical studies of PentaLyte depends on our cash resources, the costs involved, and licensing arrangements with a pharmaceutical company capable of manufacturing and marketing PentaLyte. We are currently seeking a licensee or co-developer to advance the commercialization of PentaLyte.

Hextend is manufactured and distributed in the United States by Hospira, Inc., and in South Korea by CJ CheilJedang Corp., under license from us. Summit Pharmaceuticals International Corporation has a license to develop Hextend and PentaLyte in Japan, the People's Republic of China, and Taiwan.

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Offering Summary

How to Exercise Warrants	The warrants are evidenced by warrant certificates. Warrants may be exercised by completing the purchase form on the back of the warrant certificate and delivering it, together with payment of the exercise price, to BioTime, Inc., 1301 Harbor Bay Parkway, Suite 100, Alameda, California 94502; Attention: Chief Financial Officer. Payment of the exercise price of the warrants must be made in cash or by certified or bank cashier's check or by wire transfer.
Other Terms of Warrants:	Each warrant entitles the holder to purchase one common share at a price of $10.00 per share. The warrants will expire at 5:00 p.m., New York time, on May 2, 2014 and may not be exercised after that time and date. The number of common shares and the exercise price will be proportionally adjusted in the event of a stock split, stock dividend, combination, or similar recapitalization of the common shares. The number of common shares will be adjusted according to a formula provided for in the warrants in the event that we issue rights, options, or warrants to our stockholders entitling them to purchase common shares at a price per share which is lower at the record date than the then current market price per share of common shares.
Common Shares Offered	1,383,400 outstanding common shares and 300,000 common shares issuable upon the exercise of the warrants are being offered by the selling security holders.
Warrants Offered	300,000 warrants are being offered by one of the selling security holders.

Common Shares Outstanding	47,596,130 shares as of November 5, 2010.

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RISK FACTORS

An investment in our shares and warrants involves a high degree of risk. You should purchase our shares and warrants only if you can afford to lose your entire investment. Before deciding to purchase any of the shares or warrants offered by this prospectus, you should consider the following factors which could materially adversely affect our proposed operations, our business prospects, and the value of an investment in our shares or warrants. There may be other factors that are not mentioned here or of which we are not presently aware that could also affect our operations.

Risks Related to Our Business Operations

We have incurred operating losses since inception and we do not know if we will attain profitability.

Our net losses for the three and nine months ended September 30, 2010 were $2,528,961 and $6,072,895. These do not include $2.14 million of non-recurring, non-cash financing expenses related to raising capital through stock purchase warrants. Our net losses for the fiscal years ended December 31, 2009 and 2008 were, $5,144,499 and $3,780,895, respectively, and we had an accumulated deficit of $60,984,987, $52,769,891 and $47,625,392 as of September 30, 2010, December 31, 2009, and December 31, 2008, respectively. Since inception, we have primarily financed our operations through the sale of equity securities, licensing fees, royalties on product sales by our licensees, and borrowings. Also, we have recently been awarded a research grant from the California Institute of Regenerative Medicine for a particular project. Ultimately, our ability to generate sufficient operating revenue to earn a profit depends upon our success in developing and marketing or licensing our products and technology.

During its last two fiscal years, ending March 31, 2010 and 2009, respectively, ESI, which we acquired on May 3, 2010, incurred net losses from operating activities of approximately $1.6 million and $1.9 million, respectively, before certain finance costs, gains on a derivative financial instrument, and losses attributable to ESI's minority investment in Cell Cure, and without adjustment to United States generally accepted accounting principles.

Sales of Hextend to date have not been sufficient to generate an amount of royalties or licensing fees sufficient to cover our operating expenses

Hextend is presently the only plasma expander product that we have on the market, and it is being sold only in the United States and South Korea. The royalty revenues that we have received from sales of Hextend have not been sufficient to pay our operating expenses. This means that we need to successfully develop and market or license additional products and earn additional revenues in sufficient amounts to meet our operating expenses.

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We will receive additional license fees and royalties if our licensees are successful in marketing Hextend and PentaLyte in Japan, Taiwan, and China, but they have not yet obtained the regulatory approvals required to begin selling those products.

We are also beginning to bring our first stem cell research products to the market but there is no assurance that we will succeed in generating significant revenues from the sale of those products.

We may not succeed in marketing our plasma volume expander products due to the availability of competing products

Factors that affect the marketing of our products include the following:

Hextend and our other plasma expander products will compete with other products that are commonly used in surgery and trauma care and well at lower prices.

In order to compete with other products, particularly those that sell at lower prices, our products will have to provide medically significant advantages.

Physicians and hospitals may be reluctant to try a new product due to the high degree of risk associated with the application of new technologies and products in the field of human medicine.

Competing products are being manufactured and marketed by established pharmaceutical companies. For example, B. Braun/McGaw presently markets Hespan, an artificial plasma volume expander, and Hospira and Baxter International, Inc. manufacture and sell a generic equivalent of Hespan.

There also is a risk that our competitors may succeed in developing safer or more effective products that could render our products and technologies obsolete or noncompetitive.

We will spend a substantial amount of our capital on research and development but we might not succeed in developing products and technologies that are useful in medicine

We are attempting to develop new medical products and technologies.

Many of our experimental products and technologies have not been applied in human medicine and have only been used in laboratory studies on animals. These new products and technologies might not prove to be safe and efficacious in the human medical applications for which they were developed.

The experimentation we are doing is costly, time consuming, and uncertain as to its results. We incurred research and development expenses amounting to $4,397,109, $2,968,987, and $1,725,187 during the nine months ended September 30, 2010 and the fiscal years ended December 31, 2009 and 2008, respectively.

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If we are successful in developing a new technology or product, refinement of the new technology or product and definition of the practical applications and limitations of the technology or product may take years and require the expenditure of large sums of money.

Future clinical trials of new products such as PentaLyte may take longer and may be more costly than our Hextend clinical trials. The FDA permitted us to proceed directly into a Phase III clinical trial of Hextend involving only 120 patients because the active ingredients in Hextend had already been approved for use by the FDA in other products. Because PentaLyte contains a starch that has not been approved by the FDA for use in a plasma volume expander, we have had to complete Phase I and Phase II clinical trials of PentaLyte, and we will have to complete a Phase III trial that will involve more patients than our Hextend trials. We do not yet know the scope or cost of the Phase III clinical trials that the FDA will require for PentaLyte or the other products we are developing.

Our success depends in part on the growth of the stem cell industry, which is still in its infancy, and its growth is uncertain

We are developing and marketing products for use in stem cell research, including products that we plan to sell to companies and institutions that are seeking to develop human therapeutic stem cell products.

The success of our business depends on the growth of stem cell research, without which there may be no market or only a very small market for our products and technology. The likelihood that stem cell research will grow depends upon the successful development of stem cell products that can be used to treat disease or injuries in people or that can be used to facilitate the development of other pharmaceutical products. However, stem cells have not been used in human medicine and have only been used in laboratory studies on animals.

There can be no assurance that any safe and efficacious human medical applications will be developed using stem cells or related technology.

Government-imposed restrictions and religious, moral, and ethical concerns with respect to use of embryos or human embryonic stem cells in research and development could have a material adverse effect on the growth of the stem cell industry even if research proves that useful medical products can be developed using human embryonic stem cells.

We might need to issue additional equity or debt securities in order to raise additional capital needed to pay our operating expenses

We plan to continue to incur substantial research and product development expenses, and we will need to raise additional capital to pay operating expenses until we are able to generate sufficient revenues from product sales, royalties, and license fees.

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It is likely that additional sales of equity or debt securities will be required to meet our short-term capital needs, unless we receive substantial revenues from the sale of our new products, or we are successful in licensing or sublicensing the technology that we develop or acquire from others and we receive substantial licensing fees and royalties.

Sales of additional equity securities could result in the dilution of the interests of present shareholders.

The amount and pace of research and development work that we can do or sponsor, and our ability to commence and complete clinical trials required to obtain FDA and foreign regulatory approval of our pharmaceutical products, depends upon the amount of money we have

At September 30, 2010, we had $25,421,594 of cash and cash equivalents on hand and we received $4,539,928 from the exercise of certain warrants, and $476,724 from a QTDP research grant, during the fourth quarter of 2010. In addition, during October 2010, our subsidiary Cell Cure received approximately $7,100,000 of equity financing, of which we provided $4,100,000, including $3,847,392 in cash and by converting into Cell Cure shares a $250,000 loan that we previously made to Cell Cure. However, there can be no assurance that we will be able to raise additional funds on favorable terms or at all, or that any funds raised will be sufficient to permit us to develop and market our products and technology. Unless we are able to generate sufficient revenue or raise additional funds when needed, it is likely that we will be unable to continue our planned activities, even if we make progress in our research and development projects.

We have already curtailed the pace and scope of our plasma volume expander development efforts due to the limited amount of funds available, and we may have to postpone other laboratory research and development work unless our cash resources increase through a growth in revenues or additional equity investment or borrowing.

Our business could be adversely affected if we lose the services of the key personnel upon whom we depend

Our stem cell research program is directed primarily by our Chief Executive Officer, Dr. Michael West. The loss of Dr. West’s services could have a material adverse effect on us.

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Risks Related to Our Industry

We will face certain risks arising from regulatory, legal, and economic factors that affect our business and the business of other pharmaceutical development companies. Because we are a small company with limited revenues and limited capital resources, we may be less able to bear the financial impact of these risks than larger companies that have substantial income and available capital.

If we do not receive FDA and other regulatory approvals we will not be permitted to sell our pharmaceutical products

The pharmaceutical products that we develop cannot be sold until the FDA and corresponding foreign regulatory authorities approve the products for medical use. Hextend has been approved for use in the United States, Canada, and Korea only. One of our licensees has been conducting a Phase III equivalent clinical trial of Hextend in Japan. We have conducted a Phase II clinical trial of PentaLyte as a plasma volume expander in surgery but we do not have sufficient financing to commence a Phase III trial.

The need to obtain regulatory approval to market a new product means that:

We will have to conduct expensive and time consuming clinical trials of new products. The full cost of completing a Phase III clinical trial of PentaLyte necessary to obtain FDA approval cannot be presently determined but exceeds our current financial resources.

We will incur the expense and delay inherent in seeking FDA and foreign regulatory approval of new products. For example, 12 months elapsed between the date we filed our application to market Hextend in the United States and the date on which our application was approved. Approximately 36 months elapsed between the date we filed our application for approval to market Hextend in Canada, and the date on which our application was approved, even though we did not have to conduct any additional clinical trials.

A product that is approved may be subject to restrictions on use.

The FDA can recall or withdraw approval of a product if problems arise.

We will face similar regulatory issues in foreign countries.