BIOTIME INC
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May 05, 2011

As filed with the Securities and Exchange Commission on May 5, 2011

Registration No. 333-167822

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

POST –EFFECTIVE AMENDMENT No. 1
to
FORM S-3

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

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

| | |
|---|---|
| California<br>(State or other jurisdiction of incorporation or organization) | 94-3127919<br>(I.R.S. Employer Identification Number) |
| 1301 Harbor Bay Parkway, Suite 100<br>Alameda, California 94502<br>(510) 521-3390<br>(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices) | Judith Segall, Vice-President and Secretary<br>BioTime, Inc.<br>1301 Harbor Bay Parkway, Suite 100<br>Alameda, California 94502<br>(510) 521-3390<br>(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

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. x

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

PROSPECTUS

# BIOTIME, INC.

300,000 Warrants
1,382,785 Common Shares
300,000 Common Shares Issuable Upon Exercise of Warrants

This prospectus relates to 1,382,785 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 common shares are quoted on the NYSE Amex under the symbol BTX. The closing price of the common shares on the NYSE Amex on May 4, 2011 was $6.54. There is presently no public market for the warrants offered by this prospectus.

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 8.

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 May __, 2011

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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. Initially we developed blood plasma volume expanders and related technology for use in surgery, emergency trauma treatment, and other applications. Currently we are focused on regenerative medicine, an emerging field of therapeutic product development based on recent discoveries in stem cell research.

Our lead blood plasma expander product, Hextend®, is a physiologically balanced intravenous solution used in the treatment of hypovolemia, a condition caused by low blood volume, often from blood loss during surgery or injury. Hextend maintains circulatory system fluid volume and blood pressure, and keeps vital organs perfused during surgery and trauma care.

“Regenerative medicine” refers to an emerging field of therapeutic product development that may allow all human cell and tissue types to be manufactured on an industrial scale. Historically speaking, this has never been possible in the past, and was made possible by the first isolation of human embryonic stem (“hES”) cells and creation of induced pluripotent stem (“iPS”) cells. These cells are called “pluripotent stem cells” because they have the unique property of being able to branch out into each and every kind of cell in the human body such as the cell types that make up the brain, the blood, the heart, the lungs, the liver, and other tissues. Unlike adult-derived stem cells that have limited potential to become different cell types, pluripotent stem cells may have vast potential to supply an array of new regenerative therapeutic products, especially those targeting the large and growing markets associated with age-related degenerative disease. Unlike pharmaceuticals that require a molecular target, therapeutic strategies in regenerative medicine are generally aimed at simply regenerating the affected cells and tissues, and therefore may have broader applicability.

Our efforts in regenerative medicine include the development and sale of products designed for therapeutic as well as research applications. We offer advanced human stem cell products and technology that can be used by researchers at universities, at companies in the bioscience and biopharmaceutical industries, and at other companies that provide research products to companies in those industries. Research products generally can be marketed without regulatory approval, and are therefore relatively near-term business opportunities, especially when compared to therapeutic products.

Hextend® and PentaLyte® are registered trademarks of BioTime, Inc., and ESpan™, and ESpy™ are trademarks of BioTime, Inc. ReCyte™ is a trademark of ReCyte Therapeutics, Inc. ACTCellerate™ is a trademark licensed to us by Advanced Cell Technology, Inc.

We were incorporated in 1990 in the state of California. Our principal executive offices are located at 1301 Harbor Bay Parkway, Alameda, California 94502. Our telephone number is (510) 521-3390.

Stem Cells and Products for Regenerative Medicine Research

One of our aims is to develop cell replacement therapies for age-related degenerative disease. The degenerative diseases of aging are an attractive business opportunity because the elderly comprise a large and growing segment of our population, and because many age related diseases appear to be caused by the inherent limited capacity of aged human cells to regenerate damaged tissues in the body. This latter characteristic means that age related diseases may be best treated with cell replacement therapies. The restoration of functionality in tissues through cell replacement therapy may eliminate the high costs associated with years of palliative care.

Our effort in regenerative medicine also includes research on more than 140 purified, scalable, and novel human embryonic progenitor cell types produced from hES cells. This research has included extensive gene expression studies of the unique properties of the cells, as well as conditions that cause the cells to differentiate into many of the cell types in the body. We have filed patent applications on the compositions of these cells, the media in which they can be expanded, and a variety of uses of the cells, including drug discovery and cell replacement therapies.

We have organized several subsidiaries to undertake our cell replacement therapeutic programs. We will partly or wholly fund these subsidiaries, recruit their management teams, assist them in acquiring technology, and provide general guidance for building the subsidiary companies. We may license patents and technology to the subsidiaries that we do not wholly own under agreements that will entitle us to receive royalty payments from the commercialization of products or technology developed by the subsidiaries.

Our subsidiaries, OncoCyte Corporation, OrthoCyte Corporation, ReCyte Therapeutics, Inc., Cell Cure Neurosciences Ltd, and BioTime Asia, Limited, will attempt to develop human stem cell products for therapeutic uses. We and our Singapore-based subsidiary ES Cell International Pte Ltd (“ESI”) will sell stem cell products for research use and we will license certain technology to the subsidiaries for their therapeutic product research and development programs. OncoCyte will seek 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. OrthoCyte will seek to develop cellular therapeutics for the treatment of orthopedic degenerative diseases and disorders and injuries. OrthoCyte will also sell, for research use, biocompatible hydrogels that mimic the human extracellular matrix. ReCyte will seek to develop therapeutic products for cardiovascular and blood diseases and disorders. Cell Cure Neurosciences will seek to develop therapeutic products for retinal and neurological degenerative diseases and disorders. BioTime Asia will initially seek to develop therapeutic products for the treatment of ophthalmologic, skin, musculoskeletal system, and hematologic diseases, including the targeting of genetically modified stem cells to tumors to treat cancer.

The following table shows our subsidiaries, their respective principal fields of business, our percentage ownership, and the country where their principal business is located:

| Subsidiary | Field of Business | BioTime Ownership | Country |
|---|---|---|---|
| ReCyte Therapeutics, Inc. | Blood and vascular diseases including coronary artery disease<br><br>iPS cell banking | 95.15% | USA |
| OncoCyte Corporation | Cancer | 74% | USA |
| OrthoCyte Corporation | Orthopedic diseases, including osteoarthritis<br><br>Biocompatible hydrogels that mimic the human extracellular matrix | 100% | USA |
| ES Cell International Pte. Ltd. | Stem cell products for research, including clinical GMP cell lines | 100% | Singapore |
| BioTime Asia, Ltd. | Ophthalmologic, skin, musculo-skeletal system, and hematologic diseases.<br><br>Stem cell products for research | 81% | Hong Kong |
| Cell Cure Neurosciences, Ltd. | Age-related macular degeneration<br><br>Multiple sclerosis<br><br>Parkinson's disease | 53.6% | Israel |
| LifeMap Sciences, Inc. | Stem cell data base | 100% | USA |

We and some of our subsidiaries are also developing and selling advanced human stem cell products and technologies that can be used by researchers at universities and other institutions, at companies in the bioscience and biopharmaceutical industries, and at other companies that provide research products to companies in those industries. By providing products and technologies that will be used by researchers and drug developers at larger institutions and corporations, we believe that we will be able to commercialize products more quickly and inexpensively than would be possible with the development of therapeutic products alone.

The stem cell products we are offering for research use include approximately 92 human embryonic progenitor cell ("hEPC") lines generated through the use of our ACTCellerate™ technology. We are also offering optimized ESpan™ growth media for the in vitro propagation of each hEPC line. The hEPCs are cells that are intermediate in the developmental process between embryonic stem cells and fully differentiated cells. hEPCs are expected to possess the ability to become a wide array of cell types with potential applications in research, drug discovery, and human regenerative stem cell therapies. hEPCs are relatively easy to manufacture on a large scale and in a purified state, which may make it more advantageous to work with these cells than with hES or iPS cells directly. We also plan to market additional cell types manufactured with our proprietary PureStem™ technology. PureStem™ cell lines are produced by the exogenous expression of specific transcription factors that regulate the differentiation of diverse cell types from hES or iPS cells. This technology when combined with ACTCellerate™ is expected to expand our offering of new human cell types for research and potentially therapeutic applications.

Our subsidiary, ESI, markets other stem cell research products such as human embryonic stem cell lines produced under good manufacturing practice ("GMP") - compliant conditions. During November and December 2010, we signed agreements with the California Institute for Regenerative Medicine ("CIRM") and the University of California system to distribute to California-based researchers five research-grade and GMP compliant hES cell lines produced by

ESI. We believe that making the GMP-grade cell lines available to researchers may streamline the translation of basic science into therapies. Initially, we are providing research-grade cell lines free of charge to CIRM-funded and California-based researchers until April 30, 2011. After that date, researchers will purchase the research-grade cells from us at a price of $2,600 per ampoule. We plan to make the GMP-grade cell lines, along with certain documentation and complete genomic DNA sequence information, available by November 2011. We will charge a price for the GMP-grade cell lines that covers our production and delivery costs. Although no royalties will be payable to us by researchers who acquire the cell lines for research use, researchers who desire to use the GMP cell lines for therapeutic or diagnostic products, or for any other commercial purposes, may do so only after signing commercialization agreements acceptable to us. Commercialization agreements under this program will entitle 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 commercialization of their product.

Through its recent acquisition of Glycosan BioSystems, Inc, our subsidiary OrthoCyte acquired Glycosan's line of proprietary biocompatible hydrogels that mimic the human extracellular matrix (ECM). The human ECM is a web of molecules surrounding cells that is essential to the formation, function, and growth of discrete tissues and organs in the body. Glycosan's HyStem® hydrogels have the demonstrated ability to support the growth and directed differentiation of stem cells, and are designed as injectable, resorbable matrices for tissue engineering, regenerative medicine, and for research applications involving the laboratory culture of human cells. OrthoCyte will continue the marketing of the HyStem® and other Glycosan products for research use, and may also seek regulatory approval for the use of one Glycosan hydrogel, HyStem®-Rx, as a stand-alone cell delivery device that can be used in reconstruction and cosmetic surgery and other cell transplant procedures in countries outside of the United States.

During April 2011, we organized a new subsidiary, LifeMap Sciences, Inc., to advance the development and commercialization of our embryonic stem cell database. The new expanded data will address all known human branches in the mammalian developmental tree, including several thousand stem and progenitor cells, and related information such as anatomy, differentially-expressed gene signatures, and research reagents. Our plan is to make the database available for use by stem cell researchers at pharmaceutical and biotechnology companies and other institutions through paid subscriptions or on a fee per use basis. The database will permit users to follow the development of embryonic stem cell lines to the purified progenitor cell lines created by us using our proprietary ACTCellerateTM technology.

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 is manufactured and distributed in the United States by Hospira, Inc., and in South Korea by CJ CheilJedang Corp., under license from us.

Offering Summary

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| How to Exercise Warrants | The warrants are evidenced by warrant certificates.<br><br>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.<br><br>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.<br><br>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.<br><br>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.<br><br>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 | 1,382,785 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 | 48,799,326 shares as of April 25, 2011 |

## 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 and 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 or the value of the securities offered by this prospectus.

### 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 month period ended March 31, 2011 and the fiscal years ended December 31, 2010, 2009 and 2008 were $4,032,137, $10,287,280, $5,144,499, and $3,780,895, respectively, and we had an accumulated deficit of $67,316,641 as of March 31, 2011, and $63,954,509, $52,769,891, and $47,625,392 as of December 31, 2010, 2009, and 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 been awarded a research grant from CIRM and the U.S. Government's Qualifying Therapeutic Discovery Project ("QTDP"). 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.

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 in vitro or in 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 $2,855,669, $7,892,024, $2,968,987, and $1,725,187 during the three month period ended March 31, 2011 and the fiscal years ended December 31, 2010, 2009 and 2008, respectively.

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 therapeutic products will be very expensive and will take years to complete. We may not have the financial resources to fund clinical trials on our own and we may have to enter into licensing or collaborative arrangements with larger, well-capitalized pharmaceutical companies in order to bear the cost. Any such arrangements may be dilutive to our ownership or economic interest in the products we develop, and we might have to accept a royalty payment on the sale of the product rather than receiving the gross revenues from product sales.

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

The success of our business of selling products for use in stem cell research 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. The growth in stem cell research also depends upon the availability of funding through private investment and government research grants.

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 plan to invest in the development of a stem cell data base but there is no assurance that the data base, if successfully completed, can be profitably commercialized

We recently formed a new subsidiary, LifeMap Sciences, to advance the development and commercialization of our embryonic stem cell database. We have invested approximately $833,000 in LifeMap Sciences and we plan to invest approximately $1,166,000 more by July 1, 2012 if certain database development milestones are attained and certain other conditions are met it. Our plan is to make the database available for use by stem cell researchers at pharmaceutical and biotechnology companies and other institutions through paid subscriptions or on a fee per use basis, but there is no assurance that the data base will be successfully completed or that LifeMap Sciences will be able to generate sufficient paid subscriptions for use of the data base to allow us to recover our investment or earn a profit.

Sales of our products to date have not been sufficient to generate an amount of revenue 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.

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.

Sales of our plasma volume expander products may be adversely impacted by the availability of competing products

Hextend and our other plasma expander products will compete with other products that are commonly used in surgery and trauma care and sell 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 at developing safer or more effective products that could render our products and technologies obsolete or noncompetitive.

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, largely through our subsidiaries, and we and our subsidiaries 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.

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 at 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 by us or our subsidiaries could result in the dilution of the interests of present shareholders.

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

At March 31, 2011, we had $30,136,979 of cash and cash equivalents on hand. There can be no assurance that we or our subsidiaries will be able to raise additional funds on favorable terms or at all, or that any funds raised will be sufficient to permit us or our subsidiaries to develop and market our products and technology. Unless we and our subsidiaries 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.

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 is the case with larger companies possessing substantial income and available capital.

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

The pharmaceutical and medical device products that we and our subsidiaries develop cannot be sold until the United States Food and Drug Administration ("FDA") and corresponding foreign regulatory authorities approve the products for medical use. 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 conducting and completing clinical trials necessary to obtain FDA and foreign regulatory approval of a new product cannot be presently determined, but could exceed our current financial resources.

We will incur the expense and delay inherent in seeking FDA and foreign regulatory approval of new products, even if the results of clinical trials are favorable. 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.

Data obtained from preclinical and clinical studies is susceptible to varying interpretations that could delay, limit, or prevent regulatory agency approvals. Delays in the regulatory approval process or rejections of an application for approval of a new drug may be encountered as a result of changes in regulatory agency policy.

Because the therapeutic products we are developing with hES and iPS technology involve the application of new technologies and approaches to medicine, the FDA or foreign regulatory agencies may subject those products to additional or more stringent review than drugs or biologicals derived from other technologies.

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.

Government-imposed restrictions and religious, moral, and ethical concerns about the use of hES cells could prevent us from developing and successfully marketing stem cell products

Government-imposed restrictions with respect to the use of embryos or human embryonic stem cells in research and development could limit our ability to conduct research and develop new products.

Government-imposed restrictions on the use of embryos or hES cells in the United States and abroad could generally constrain stem cell research, thereby limiting the market and demand for our products. During March 2009, President Obama lifted certain restrictions on federal funding of research involving the use of hES cells, and in accordance with President Obama's Executive Order, the National Institutes of Health ("NIH") has adopted new guidelines for determining the eligibility of hES cell lines for use in federally funded research. The central focus of the proposed guidelines is to assure that hES cells used in federally funded research were derived from human embryos that were created for reproductive purposes, were no longer needed for this purpose, and were voluntarily donated for research purposes with the informed written consent of the donors. The hES cells that were derived from embryos created for research purposes rather than reproductive purposes, and other hES cells that were not derived in compliance with the guidelines, are not eligible for use in federally funded research. A lawsuit, Sherley v. Sebelius, is now pending, challenging the legality of the new NIH guidelines. In that litigation, a United States District Court issued a temporary injunction against the implementation of the new NIH guidelines, but the District Court's ruling has been vacated by the United States Court of Appeals. The ultimate resolution of that lawsuit could determine whether the federal government may fund research using hES cells, unless new legislation is passed expressly permitting or prohibiting such funding.

California law requires that stem cell research be conducted under the oversight of a stem cell research oversight committee ("SCRO"). Many kinds of stem cell research, including the derivation of new hES cell lines, may only be conducted in California with the prior written approval of the SCRO. A SCRO could prohibit or impose restrictions on the research that we plan to do.

The use of hES cells gives rise to religious, moral, and ethical issues regarding the appropriate means of obtaining the cells and the appropriate use and disposal of the cells. These considerations could lead to more restrictive government regulations or could generally constrain stem cell research, thereby limiting the market and demand for our products.

If we are unable to obtain and enforce patents and to protect our trade secrets, others could use our technology to compete with us, which could limit opportunities for us to generate revenues by licensing our technology and selling products

Our success will depend in part on our ability to obtain and enforce patents and maintain trade secrets in the United States and in other countries. If we are unsuccessful at obtaining and enforcing patents, our competitors could use our technology and create products that compete with our products, without paying license fees or royalties to us.

The preparation, filing, and prosecution of patent applications can be costly and time consuming. Our limited financial resources may not permit us to pursue patent protection of all of our technology and products throughout the world.

Even if we are able to obtain issued patents covering our technology or products, we may have to incur substantial legal fees and other expenses to enforce our patent rights in order to protect our technology and products from infringing uses. We may not have the financial resources to finance the litigation required to preserve our patent and trade secret rights.

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There is no certainty that our pending or future patent applications will result in the issuance of patents

We have filed patent applications for technology that we have developed, and we have obtained licenses for a number of patent applications covering technology developed by others, that we believe will be useful in producing new products, and which we believe may be of commercial interest to other companies that may be willing to sublicense the technology for fees or royalty payments. In the future, we may also file additional new patent applications seeking patent protection for new technology or products that we develop ourselves or jointly with others. However, there is no assurance that any of our licensed patent applications, or any patent applications that we have filed or that we may file in the future covering our own technology, either in the United States or abroad, will result in the issuance of patents.

In Europe, the European Patent Convention prohibits the granting of European patents for inventions that concern "uses of human embryos for industrial or commercial purposes." The European Patent Office is presently interpreting this prohibition broadly, and is applying it to reject patent claims that pertain to human embryonic stem cells. However, this broad interpretation is being challenged through the European Patent Office appeals system. As a result, we do not yet know whether or to what extent we will be able to obtain patent protection for our human embryonic stem cell technologies in Europe.

The process of applying for and obtaining patents can be expensive and slow

The preparation and filing of patent applications, and the maintenance of patents that are issued, may require substantial time and money.

A patent interference proceeding may be instituted with the United States Patent and Trademark Officer ("U.S. PTO") when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent. At the completion of the interference proceeding, the PTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex, highly contested legal proceedings, and the PTO's decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delay in obtaining a patent, and if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us.

Oppositions to the issuance of patents may be filed under European patent law and the patent laws of certain other countries. As with the U.S. PTO interference proceedings, these foreign proceedings can be very expensive to contest and can result in significant delays in obtaining a patent or can result in a denial of a patent application.

Our patents may not protect our products from competition

We or our subsidiaries have patents in the United States, Canada, the European Union countries, Australia, Israel, Russia, South Africa, South Korea, Japan, Hong Kong, and Singapore, and have filed patent applications in other foreign countries for our plasma volume expander and stem cell products and technology.

We might not be able to obtain any additional patents, and any patents that we do obtain might not be comprehensive enough to provide us with meaningful patent protection.

There will always be a risk that our competitors might be able to successfully challenge the validity or enforceability of any patent issued to us.

In addition to interference proceedings, the U.S. PTO can re-examine issued patents at the request of a third party seeking to have the patent invalidated. This means that patents owned or licensed by us may be subject to re-examination and may be lost if the outcome of the re-examination is unfavorable to us.

We may be subject to patent infringement claims that could be costly to defend, which may limit our ability to use disputed technologies, and which could prevent us from pursuing research and development or commercialization of some of our products

The success of our business depends significantly on our ability to operate without infringing patents and other proprietary rights of others. If the technology that we use infringes a patent held by others, we could be sued for monetary damages by the patent holder or its licensee, or we could be prevented from continuing research, development, and commercialization of products that rely on that technology, unless we are able to obtain a license to use the patent. The cost and availability of a license to a patent cannot be predicted, and the likelihood of obtaining a license at an acceptable cost would be lower if the patent holder or any of its licensees is using the patent to develop or market a product with which our product would compete. If we could not obtain a necessary license, we would need to develop or obtain rights to alternative technologies, which could prove costly and could cause delays in product development, or we could be forced to discontinue the development or marketing of any products that were developed using the technology covered by the patent.

If we fail to meet our obligations under license agreements, we may lose our rights to key technologies on which our business depends

Our business depends on several critical technologies that are based in part on technology licensed from third parties. Those third-party license agreements impose obligations on us, including payment obligations and obligations to pursue development of commercial products under the licensed patents or technology. If a licensor believes that we have failed to meet our obligations under a license agreement, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of potential products, and our ability to raise any capital that we might then need, could be significantly and negatively affected. If our license rights were restricted or ultimately lost, we would not be able to continue to use the licensed technology in our business.

The price and sale of our products may be limited by health insurance coverage and government regulation

Success in selling our pharmaceutical products may depend in part on the extent to which health insurance companies, HMOs, and government health administration authorities such as Medicare and Medicaid will pay for the cost of the products and related treatment. Presently, most health insurance plans and HMO