

BIOTIME INC  
Form 424B3  
June 24, 2010

Filed Pursuant to Rule 424(b)(3)  
Registration Statement No. 333-166862

PROSPECTUS

## **BIOTIME, INC.**

# **7,674,801 Warrants 7,094,282 Common Shares 7,799,801 Common Shares Issuable Upon Exercise of Warrants and Options**

We are offering the holders of all of our common share purchase warrants that expire on October 31, 2010 the opportunity to exercise their warrants at a discounted exercise price for a limited period of time. Until 5:00 p.m. New York Time on August 18, 2010 (the discount offer expiration time), we will allow the warrants to be exercised at an exercise price of \$1.818 per share. This represents a discount of \$0.182 per share from the regular exercise price of \$2.00 per share. In this prospectus, the term discount offer means the opportunity of warrant holders to exercise their warrants at the discounted price of \$1.818 per share. After the discount offer expires, warrant holders who continue to hold warrants will be able to exercise their remaining warrants at the regular exercise price of \$2.00 per share until the warrants expire on October 31, 2010.

The common shares are quoted on the NYSE Amex under the symbol BTIM, and the warrants are quoted on the NYSE Amex under the symbol BTIM.WS. The closing price of the common shares on the NYSE Amex on June 17, 2010 was \$7.02, and the closing price of the warrants on the NYSE Amex on June 17, 2010 was \$4.98.

The warrants that are subject to the discount offer include 6,850,152 warrants that we issued in connection with our subscription rights offers that were completed during January 2004 and December 2005, and 724,649 warrants that we issued in private transactions. The 7,574,801 common shares issuable upon the exercise of those warrants are also included in this prospectus.

Of the 7,574,801 warrants that are subject to the discount offer, 3,836,997 warrants are held by certain selling security holders, as discussed elsewhere in this prospectus, and 3,737,804 warrants are held by public warrant holders. This prospectus also relates to 7,094,282 outstanding common shares and 125,000 options, and the common shares that may be issued upon the exercise of the options, held by some of the selling security holders. In addition, this prospectus relates to other warrants, and 100,000 common shares that may be issued upon the exercise of those warrants at an exercise price of \$0.68 per share, held by a non-profit organization (the ILC Warrants). References in this prospectus to the warrants exclude the ILC Warrants. The ILC Warrants will not be listed on a national securities exchange, are not expected to be traded in the over-the-counter market, and are not subject to the discount offer described in this prospectus. We will receive the exercise price of the warrants, the ILC Warrants, and the options when those securities are exercised. However, all of the net proceeds from the sale of common shares, warrants, and ILC Warrants by the selling security holders will belong to the selling security holders and not to us.

The selling security holders named in this prospectus and their designees may sell their common shares and warrants from time to time on the NYSE Amex at prevailing market prices, or in privately negotiated transactions, and they will bear all broker-dealer fees, commissions, and discounts payable in connection with the sale of their shares and warrants.

**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 June 18, 2010

---

## 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, plans, 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. Our first business segment is 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.

Our second business segment is 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., BioTime Asia, Limited, and our recently acquired subsidiary ES Cell International Pte. Ltd.

We have also initiated development programs for human therapeutic applications of hES and iPS cells, focused primarily on the treatment of cancer, ophthalmologic, skin, musculo-skeletal system, and hematologic diseases. Cancer research and development programs will be conducted in the United States by our subsidiary OncoCyte Corporation. Our newly formed subsidiary OrthoCyte Corporation will work to develop therapeutic applications of stem cells to treat orthopedic diseases and injuries. BioTime Asia, Limited, a subsidiary formed as a Hong Kong corporation, will conduct research and development programs in the People's Republic of China for the treatment of cancer and other diseases.

On May 3, 2010, we acquired ES Cell International Pte Ltd, a Singapore private limited company ( ESI ). 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. More recently, ESI has produced an additional six new clinical-grade human embryonic stem cell lines that were derived following principles of good manufacturing practice ( GMP ) and currently

offers them for potential use in therapeutic product development.

During 2009, we were awarded a \$4,721,706 grant from the California Institute of Regenerative Medicine ( CIRM ) for a stem cell research project related to our ACTCellerate™ embryonic stem cell technology that will address the need for industrial scale production of purified therapeutic cells for human therapeutic uses.

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.

1

---

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™, 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, diabetes, arthritis, and other orthopedic diseases and injuries.

On March 16, 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, 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.

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, Inc. and BioTime Asia, Limited. We are presently offering for sale 13 novel ACTCellerate™ hEPC lines and optimized ESpan™ growth media for the *in vitro* propagation of those hEPC lines. 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 ACTCellerate™ hEPC lines and the optimized ESpan™ growth media for the *in vitro* propagation of those hEPC lines. The companies anticipate jointly

launching 29 additional hEPC lines and associated ESpan™ growth media within the coming 12 months. Our stem cell products 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

2

---

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* during 2010. 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*.

Our initial efforts to develop therapeutic stem cell products are being conducted through three subsidiaries, BioTime Asia, Limited, OncoCyte Corporation, and OrthoCyte Corporation. 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 a plastic 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 Corporation 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 Corporation, 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 will transfer or license certain patents and technology to OrthoCyte for use in the field of orthopedic therapies. OrthoCyte will initially work with ACTCellerate 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 ACTCellerat<sup>EM</sup> and ReCyte<sup>TM</sup> 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.

There is no assurance that BioTime Asia, OncoCyte, OrthoCyte, or ESI 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 by 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.

## **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.

## **Purpose of the Discount Offer**

We have determined that it would be beneficial for us to raise additional capital at this time to finance our operations, including:

Research and development work by our subsidiary, OncoCyte Corporation, to develop stem cell products for the treatment of cancer;

Research and development work by our new subsidiary OrthoCyte Corporation to develop stem cell products for the treatment of arthritis and other diseases and injuries of the musculoskeletal system;

Continued research and product development work by us and our subsidiaries, Embryome Sciences, ESI, and BioTime Asia, or by Cell Cure Neurosciences, Limited;

Conducting new clinical trials of Hextend and PentaLyte;

General and administrative expenses.

We are making the discount offer to raise additional capital without significant dilution of the ownership interests of

existing shareholders or warrant holders since the exercise of warrants in the discount offer will not involve the issuance of new warrants. Warrant holders who exercise their warrants will be able to purchase shares at a price below market without incurring broker's commissions. Because participation in the discount offer is optional, warrant holders may still elect to continue to hold their warrants without exercising them at this time, or they may sell them on the NYSE Amex from time to time.

4

---

We intend to use a substantial portion of any proceeds we receive from the exercise of the warrants to finance our research and development programs. However, we cannot predict in advance how many warrants will be exercised or when they will be exercised. 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 products, depends upon the amount of money we have. Future research and clinical study costs are not presently determinable due to many factors, including the inherent uncertainty of these costs and the uncertainty as to timing, source, and amount of capital that will become available for these projects.

## Offering Summary

### Discount Offer

Under the discount offer, the warrants may be exercised at a price of \$1.818 until the discount offer expiration time.

### Discount Offer Expiration Time

The discount offer will expire at 5:00 p.m. New York Time on August 18, 2010.

### How to Exercise Warrants

The warrants are evidenced by warrant certificates.

You may exercise your warrants by completing the purchase form on the back of the warrant certificate and delivering it, together with payment of the exercise price, to the warrant agent, American Stock Transfer & Trust Company, 6201 15<sup>th</sup> Avenue, Brooklyn, New York 11219.

Your signature on the purchase form must be guaranteed by a financial institution that is a participant in a recognized signature guarantee program.

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.

During the discount offer only, you may also exercise your warrants by notice of guaranteed delivery. See The Discount Offer and Description of the Warrants Payment of Exercise Price.

If your warrants are held in the name of Cede & Co. as nominee for The Depository Trust Company, or in the name of any other depository or nominee, you should contact your broker-dealer or other financial institution that holds your warrants and direct them to exercise them on your behalf.

### Amendment, Extension, or Termination of the Discount Offer

BioTime may, in its sole discretion: (a) terminate the discount offer; (b) extend the discount offer expiration time to a later date; or (c) amend or modify the terms of the discount offer.

### Participation by Directors and their Affiliates

The members of our Board of Directors and their affiliates who own warrants may exercise their warrants in the discount offer on the same terms as other warrant holders.

### Other Terms of Warrants:

Each warrant entitles the holder to purchase one common share at a price of \$2.00 per share, except for warrants exercised in the discount offer.

The warrants will expire at 5:00 p.m. on October 31, 2010 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.

6

---

We may redeem the warrants by paying \$.05 per warrant if the closing price of the common shares on the NYSE Amex exceeds 200% of the exercise price of the warrants for any 20 consecutive trading days. We will give the warrant holders 20 days written notice of the redemption, setting the redemption date, and the warrant holders may exercise the warrants prior to the redemption date. The warrants may not be exercised after the last business day prior to the redemption date.

Common Shares Offered

7,799,801 common shares are being offered by us upon the exercise of the warrants, options, and the ILC Warrants.

7,094,282 outstanding common shares are being offered by the selling security holders.

Warrants Offered

7,574,801 warrants and the ILC Warrants are being offered by the selling security holders.

Common Shares Outstanding

39,908,164 as of May 7, 2010.

7

---

## 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 months ended March 31, 2010 and the fiscal years ended December 31, 2009 and 2008 were \$1,286,764, \$5,144,499 and \$3,780,895, respectively, and we had an accumulated deficit of \$54,056,655, \$52,769,891 and \$47,625,392 as of March 31, 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.

ESI, which we acquired on May 3, 2010, incurred net losses from operations of approximately \$3.4 million (unaudited) and \$3.26 million, without adjustment to United States generally accepted accounting principles, during its last two fiscal years, ending March 31, 2010 and 2009, respectively. However, financing costs related to the ESI promissory notes that we acquired contributed approximately \$2.3 million (unaudited) and \$0.94 million, respectively, to the net loss during each of those fiscal years. Interest on those notes will be eliminated in the consolidation of ESI's financial statements with our own. Upon completion of the acquisition of ESI, BioTime became the owner of the ESI promissory notes, so that these notes have become an inter-company obligation of ESI payable to BioTime. We have therefore acquired ESI essentially free of indebtedness to third parties, and we have incurred no debt obligations of our own as a result of the acquisition.

#### **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.

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 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.

8

---

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 \$1,159,951, \$2,968,987, and \$1,725,187 during the three months ended March 31, 2010 and the fiscal years ended December 31, 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 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.

It is likely that additional sales of equity or debt securities will be required to meet our short-term capital needs, unless a substantial portion of the warrants are exercised, or 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**

We intend to use a substantial portion of any proceeds we receive from the exercise of the warrants to finance our research and development programs. However, we cannot predict in advance how many warrants will be exercised or when they will be exercised.

During 2009, we were awarded a \$4,721,706 grant for a stem cell research project, and we received \$8,000,000 through the sale of stock and warrants, and our subsidiary OncoCyte Corporation received \$4,000,000 through the sale of stock. During May 2010, we received \$8,000,000 through the exercise of warrants by two private investors. 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.

## **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.

### **Government imposed restrictions and religious, moral, and ethical concerns on 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 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.

California law requires that stem cell research be conducted under the oversight of a stem cell research oversight ( SCRO ) committee. 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 in 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.

Government imposed restrictions and religious, moral, and ethical concerns on the use of hES cells could prevent u



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.

**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. We may also file additional new patent applications in the future 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, in the United States or abroad will result in the issuance of patents.