

BIOTIME INC

Form 424B5

June 15, 2016

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**The information in this preliminary prospectus supplement and the accompanying prospectus is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are part of an effective registration statement filed with the Securities and Exchange Commission. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell, nor do they seek an offer to buy, these securities in any jurisdiction where the offer or sale is not permitted.**

**Filed Pursuant to Rule 424(b)(5)**

**Registration No. 333-201824**

**SUBJECT TO COMPLETION, DATED JUNE 15, 2016**

**PRELIMINARY PROSPECTUS SUPPLEMENT**

(To Prospectus dated February 12, 2015)

**Shares**

**Common Stock**

We are offering \_\_\_\_\_ shares of our common stock, no par value. Our common stock is listed on the NYSE MKT and on the Tel Aviv Stock Exchange under the symbol **BTX**. On June 14, 2016, the last reported sale price for our common stock on the NYSE MKT was \$2.62 per share.

One of our significant stockholders has indicated an interest in purchasing up to an aggregate of \$6 million in shares of our common stock in this offering at the offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to this stockholder, or the stockholder may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount of any shares purchased by this stockholder as they will on any other shares sold to the public in this offering.

**Investing in our common stock involves risks. See **Risk Factors** beginning on page **S-5** of this prospectus supplement, on page **6** of the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement.**

	<b>Per Share</b>	<b>Total</b>
Public Offering Price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds to us, before expenses	\$	\$

(1) We have also agreed to reimburse the underwriters for certain of their expenses. See **Underwriting** on page **S-27** of this prospectus supplement for more information about these arrangements.

We have granted an over-allotment option to the underwriters. Under this option, the underwriters may elect to purchase a maximum of \_\_\_\_\_ additional shares of common stock from us within 30 days following the date of this prospectus supplement to cover over-allotments. If the underwriters exercise the option in full, the total underwriting discount payable by us will be \$ \_\_\_\_\_, and the total proceeds to us, before expenses, will be \$ \_\_\_\_\_.

We expect to deliver the shares against payment on or about June , 2016.

**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 supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.**

*Sole Book-Running Manager*

**Oppenheimer & Co.**

The date of this prospectus supplement is June , 2016

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**You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus and any free writing prospectuses we may provide to you in connection with this offering. We have not, and the underwriters have not, authorized any other person to provide you with any information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus supplement, the accompanying prospectus, the**

**documents incorporated by reference herein and any free writing prospectuses we may provide to you in connection with this offering is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed since those dates. You should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus supplement outside the United States. Furthermore, you should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.**

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**ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the U.S. Securities and Exchange Commission, or SEC, utilizing a shelf registration process. This document is in two parts. The first part is this prospectus supplement, which describes the terms of the offering of the securities offered hereby and also adds to and updates the information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part is the accompanying prospectus, which provides more general information, some of which may not apply to this offering and some of which may have been supplemented or superseded by information in this prospectus supplement or documents incorporated or deemed to be incorporated by reference in this prospectus supplement that we filed with the SEC subsequent to the date of the prospectus. To the extent that there is any conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference herein or therein, on the other hand, you should rely on the information in this prospectus supplement.

You should rely only on the information contained in this prospectus supplement, contained in the accompanying prospectus or incorporated herein or therein by reference. We have not authorized anyone to provide you with information that is different. We are offering to sell, and seeking offers to buy, the securities offered hereby only in jurisdictions where offers and sales are permitted. The information contained, or incorporated by reference, in this prospectus supplement and contained, or incorporated by reference, in the accompanying prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus, or of any sale of our shares of common stock. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents we have referred you to in the section entitled "Where You Can Find More Information" and "Incorporation of Certain Information by Reference" below.

We own or have rights to trademarks or trade names that we use in conjunction with the operation of our business. Each trademark, trade name or service mark of any other company appearing in this prospectus supplement or the accompanying prospectus belongs to its holder. Use or display by us of other parties' trademarks, trade names or service marks is not intended to and does not imply a relationship with, or endorsement or sponsorship by us of, the trademark, trade name or service mark owner.

The industry and market data contained or incorporated by reference in this prospectus supplement are based either on our management's own estimates or on independent industry publications, reports by market research firms or other published independent sources. Although we believe these sources are reliable, we have not independently verified the information and cannot guarantee its accuracy and completeness, as industry and market data are subject to change and cannot always be verified with complete certainty due to limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties inherent in any statistical survey of market shares. Accordingly, you should be aware that the industry and market data contained or incorporated by reference in this prospectus supplement, and estimates and beliefs based on such data, may not be reliable. Unless otherwise indicated, all information contained or incorporated by reference in this prospectus supplement concerning our industry in general or any segment thereof, including information regarding our general expectations and market opportunity, is based on management's estimates using internal data, data from industry related publications, consumer research and marketing studies and other externally obtained data.

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### **PROSPECTUS SUPPLEMENT SUMMARY**

*This summary highlights certain information about this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our shares of common stock. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the Risk Factors section contained in this prospectus supplement and the other documents incorporated by reference into this prospectus supplement and in the accompanying prospectus. References to we, us, and our mean BioTime, Inc. and our subsidiaries unless the context otherwise indicates. In this regard, references to we, us, and our in the context of rights or obligations under any contract or agreement mean BioTime, Inc. only and not our subsidiaries.*

### **Business Overview**

We are a clinical-stage biotechnology company focused on developing and commercializing novel therapies in the field of regenerative medicine. Regenerative medicine utilizes advances in stem cell biology, biomaterials, lab-generated cells and tissues, and biologics to engineer and provide healthy cells, tissues and organs to patients with chronic degenerative diseases. To that end, we have obtained a collection of pluripotent stem cell assets and the technology for the delivery and engraftment of such cells. Pluripotent stem cells are capable of becoming any cell type in the human body. Pluripotent stem cells allow for the manufacture of all human cell types on an industrial-scale. Unlike adult stem cells, our focus is on clinical grade master cell banks of pluripotent stem cells that propagate indefinitely as a source of product. Cell types derived from pluripotent stem cells have potential application in many areas of medicine with large unmet patient needs, including various age-related degenerative diseases and degenerative conditions for which there presently are no cures. Unlike pharmaceuticals which almost always require a molecular target, therapeutic strategies based on the use of cell types derived from pluripotent stem cells are generally aimed at regenerating or replacing affected cells and tissues, and therefore may have broader applicability than pharmaceutical products. Our collection of pluripotent stem cell assets is complemented by our *HyStem*<sup>®</sup> technology, which delivers and engrafts cells derived from pluripotent stem cells or the patient's own somatic or adult stem cells, to or at the desired location.

In order to efficiently advance product candidates through the clinical trial process, we have historically created operating subsidiaries for each program and product line. Our management believes this approach has fostered efficient use of resources and reduced shareholder dilution as compared to strategies commonly deployed by the biotechnology industry, as the various programs and product lines have advanced through basic research and animal studies. As a result, we have been able to develop multiple clinical-stage products rather than being dependent on a single product program. We and some of our subsidiaries have also received substantial amounts of non-dilutive financial support from government and nonprofit organizations that are seeking, based on rigorous scientific review processes, to identify and accelerate the development of potential breakthroughs in the treatment of various major diseases.

As of March 31, 2016, we held, directly and indirectly through subsidiaries and equity method investments, interests in 10 operating entities located throughout the world. In the United States, we own interests in Ascendance Biotechnology, Inc., or Ascendance, Asterias Biotherapeutics, Inc., or Asterias, (NYSE MKT: AST), LifeMap Sciences, Inc., or LifeMap Sciences, LifeMap Solutions, Inc., or LifeMap Solutions, OncoCyte Corporation, or OncoCyte, (NYSE MKT: OCX), OrthoCyte Corporation, or OrthoCyte, and ReCyte Therapeutics, Inc., or ReCyte.

We hold an approximate 46% interest in Ascendance, a company that manufactures and sells proprietary products and services that assay new drug candidates for potential toxicity, including *HepatoPac*<sup>®</sup> and *HepatoMune*<sup>®</sup>, and other products for use as research tools by a range of customers, including several leading global pharmaceutical companies.

We hold an approximate 49% interest in Asterias, whose principal field of business involves therapeutic products derived from pluripotent stem cells, and immunotherapy products. Asterias' clinical programs include AST-OPC1 for spinal cord injury, AST-VAC1 for acute myelogenous leukemia and AST-VAC2 for non-small cell lung cancer. We hold an approximate 78% interest in LifeMap Sciences, whose principal field of business involves biomedical, gene, disease, and stem cell databases and research tools. We indirectly hold interests in LifeMap Solutions, a mobile health software company, and LifeMap Sciences, Ltd., a company located in Israel that develops biomedical, gene, disease, and stem cell databases and research tools, each of which are wholly-owned subsidiaries of LifeMap Sciences.

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We hold an approximate 58% interest in OncoCyte, whose principal field of business involves proprietary non-invasive, liquid biopsy and diagnostics for lung, breast and bladder cancers. We wholly own OrthoCyte, whose principal field of business involves bone grafting products for orthopedic diseases and injuries. Lastly, we hold an approximate 95% interest in ReCyte, whose principal field of business involves stem cell-derived endothelial and cardiovascular related progenitor cells for the treatment of vascular disorders, ischemic conditions and brown adipocytes for type-2 diabetes and obesity.

In Singapore, we wholly own ES Cell International Pte Ltd., or ES Cell, an entity that utilizes stem cell products for research, including clinical grade cell lines produced under current good manufacturing procedures.

In Israel, we hold an approximate 63% interest in Cell Cure Neurosciences Ltd., or Cell Cure Neurosciences, an entity that develops products to treat age-related macular degeneration, or AMD, and other neurological diseases. According to the Angiogenesis Foundation, AMD afflicts over 30 million people worldwide. AMD takes two forms, a dry form and a wet form. The dry form of AMD occurs when the light-sensitive cells in the macula of the eye break down due to the death of a supporting cell type called retinal pigment epithelial cells, impairing central vision and sometimes leading to blindness. Approximately 90% of AMD prevalence is the dry form of the disease, while the wet form afflicts only about 10% of patients. Nevertheless, the market for therapeutics for the wet form of AMD is approximately \$5 billion globally. According to the National Institutes of Health, the dry form of AMD is a leading cause of blindness in people over age 60. In addition, it is estimated that approximately 1.6 million new cases of the dry form of AMD develop in the United States each year. Cell Cure Neurosciences' lead product is *OpRegen*<sup>®</sup>, which is a potential therapy derived from pluripotent stem cells for the treatment of the dry form of AMD.

In addition, we are currently developing *Renevia*<sup>®</sup> as a potential treatment for HIV related facial lipoatrophy, a syndrome that occurs in HIV-infected patients who are being treated with antiretroviral medications. Approximately 350,000 people in Europe have HIV-related lipoatrophy or facial wasting. We plan to apply for CE Mark approval in Europe in the second quarter of 2017. In addition, we intend to complete enrollment for a pivotal trial in the United States during the third quarter of 2016 and initiate that trial during the first half of 2017. *Renevia*<sup>®</sup> may address an immediate need in cosmetic and reconstructive surgeries and other procedures by improving the process of transplanting adipose fat derived cells or other cells. Cell types such as adipose stem cells obtained from a patient through liposuction can be transplanted back into the same patient at another location in the body, without the risk of rejection associated with the transplant of donor tissues. Over time, we may discover that *Renevia*<sup>®</sup> has much broader applications beyond its use in patients with HIV. It is estimated that the global facial aesthetics market was valued at \$2.5 billion in 2013 and is expected to reach \$5.4 billion by 2020. In addition, in 2014 there were approximately 1 million augmentation or reconstruction surgical procedures performed in the United States. We believe there are approximately half a million procedures per year in which *Renevia*<sup>®</sup> could possibly be utilized apart from the current developed use as a potential treatment for HIV related facial lipoatrophy. Such procedures include approximately 70,000 facial fat transfer procedures, approximately 220,000 liposuction procedures, approximately 125,000 rhytidectomy procedures, and approximately 125,000 abdominoplasty procedures. In addition, we believe *Renevia*<sup>®</sup> may be able to serve as a premium alternative to dermal fillers, of which approximately 2.3 million procedures are performed in the United States per year. We believe *Renevia*<sup>®</sup> has the potential for better, long-lasting and more natural outcome than fillers by enabling the growth of new facial tissue.

This revolution in medical science changes the focus from treating the symptoms of chronic and degenerative diseases to providing actual cures. There is no general approval path for use of pluripotent stem cells, however, there is uniformity for product and genotype. Together with our subsidiaries, we are advancing two late-stage pivotal trials and a robust pipeline which includes the following programs:

- *OpRegen*<sup>®</sup> is in a Phase I/IIa clinical trial to treat the dry form of AMD.
-

AST-OPC1, a potential therapy derived from pluripotent stem cells, is in a Phase I/IIa trial for spinal cord injury rehabilitation and AST-VAC2 is advancing toward clinical development for non-small cell lung cancer, both pluripotent stem cell-based therapies being developed by Asterias.

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- Our collaborator Cancer Research UK is preparing to initiate a Phase I/II clinical trial of AST-VAC2 in non-small cell lung cancer representing a second generation, allogeneic approach to cancer immunotherapy.
- Other therapies derived from pluripotent stem cells that are in pre-clinical development include an innovative bone grafting therapy and potential treatments for a variety of cardiovascular and related ischemic disorders. AST-VAC1, a cancer immunotherapy with promising Phase II clinical trial data in acute myeloid leukemia, or AML. Asterias currently plans to submit a request for a Special Protocol Assessment, or SPA, to the U.S. Food and Drug Administration, or FDA, to confirm the primary endpoint and other design elements of this pivotal Phase 3 trial.
- *Renovia*<sup>®</sup> is currently in a pivotal clinical trial in Europe to assess its efficacy in restoring normal skin contours in patients whose subcutaneous fat, or adipose tissue, has been lost due to antiviral drug treatment for HIV. If the clinical trial proceeds as anticipated, *Renovia*<sup>®</sup> has the potential to obtain regulatory approval in Europe in the second half of 2017.
- OncoCyte is developing a next generation of diagnostic tests that will be liquid biopsies using blood or urine samples. Its initial liquid biopsy products will be confirmatory diagnostics for detecting lung, bladder and breast cancer. OncoCyte's diagnostic tests are based on a proprietary set of genetic markers broadly expressed in numerous types of cancer.
- LifeMap Sciences is currently developing and marketing technology healthcare solutions, such as an integrated online database and other software research tools for biomedical and stem cell research. LifeMap Solutions is also developing mobile health (mHealth) products.
- cGMP-compliant human embryonic stem cell lines are available for research and clinical studies through our subsidiary ES Cell.
- *Hextend*<sup>®</sup>, our FDA-approved blood plasma expander, is marketed in collaboration with Hospira, Inc. in the United States and under an agreement with CJ Corporation in South Korea.

### **Company Information**

We were incorporated in the State of California on November 30, 1990. Our common stock is listed on the NYSE MKT and the Tel Aviv Stock Exchange under the symbol BTX. The address of our principal executive office is 1010 Atlantic Avenue, Suite 102, Alameda, California 94501, and our phone number at that address is 510-521-3390. Our corporate website address is [www.biotimeinc.com](http://www.biotimeinc.com). The information contained on our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus supplement.

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**THE OFFERING**

**Shares of common stock offered**

shares

**Underwriters overallotment option..**

shares

**Shares of common stock to be outstanding after this offering**

shares

**Use of proceeds**

We intend to use the net proceeds from this offering to fund our research and development activities and for working capital and other general corporate purposes. See **Use of Proceeds** on page S-24.

**Risk factors**

See **Risk Factors** beginning S-5 of this prospectus supplement, on page 6 of the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement for a discussion of factors you should consider carefully before investing in our common stock.

**NYSE MKT Symbol**

BTX

Unless we indicate otherwise, all information in this prospectus supplement is based on 94,894,140 shares of common stock issued and outstanding as of March 31, 2016 and excludes as of that date:

- warrants to purchase 9,394,862 shares of common stock at a weighted average exercise price of \$4.55 per share;
- options under our 2002 Stock Option Plan and our 2012 Equity Incentive Plan to purchase 5,453,979 shares of common stock, with a weighted average exercise price of \$3.81 per share; and
- 4,898,879 shares of common stock available for issuance under our 2002 Stock Option Plan and our 2012 Equity Incentive Plan.

Unless otherwise indicated, all information in this prospectus supplement assumes no exercise by the underwriters of their overallotment option.

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### **RISK FACTORS**

*Investing in our common stock involves risk. Before deciding whether to invest in our shares of common stock, you should consider carefully the risks and uncertainties described below and discussed under the section entitled "Risk Factors" on page 5 of the accompanying prospectus. You should also consider the risks, uncertainties and assumptions discussed under the heading "Risk Factors" included in our most recent annual report on Form 10-K, as amended, as revised or supplemented by our most recent quarterly report on Form 10-Q, each of which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. If any of these risks actually occurs, our business, business prospects, financial condition or results of operations could be seriously harmed. This could cause the trading price of our shares of common stock to decline, resulting in a loss of all or part of your investment. Please also read carefully the section below entitled "Disclosure Regarding Forward-Looking Statements."*

#### **Risks Related to This Offering**

***You will experience immediate and substantial dilution in the book value per share of the shares of common stock you purchase and may experience further dilution in the future.***

The public offering price of the common stock offered pursuant to this prospectus supplement is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of common stock in this offering, you will incur immediate and substantial dilution in the pro forma net tangible book value per share of common stock from the price per share that you pay for the common stock. See the section entitled "Dilution" below for a more detailed discussion of the dilution you will incur if you purchase shares in this offering. Furthermore, we expect that we will seek to raise additional capital from time to time in the future. Such financings may involve the issuance of equity and/or securities convertible into or exercisable or exchangeable for our equity securities. We also expect to continue to utilize equity-based compensation. To the extent the warrants and options are exercised or we issue common stock, preferred stock, or securities such as warrants that are convertible into, exercisable or exchangeable for, our common stock or preferred stock in the future, you may experience further dilution.

***Management will have broad discretion as to the use of the proceeds from this offering, and may not use the proceeds effectively.***

Our management will have broad discretion as to the application of the net proceeds from this offering. Our management may, among other possible uses of proceeds, use proceeds to finance clinical trials of products we are developing, to finance our research and develop programs, to acquire one or more businesses or new business assets, and for general working capital, and we may invest proceeds in one or more of our existing subsidiaries, or in any new subsidiaries that we may form. We may use the proceeds for purposes that are not contemplated at the time of the offering. All of these potential uses of proceeds involve risks and may not improve the performance or prospects of our business or the business or prospects of our subsidiaries, and may not increase the market value of our shares of common stock.

#### **Risks Related to Our Business Operations**

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

Our total comprehensive losses for the fiscal years ended December 31, 2015, 2014, and 2013 were \$47.8 million, \$36.4 million, and \$43.8 million, respectively, and we had an accumulated deficit of \$246.3 million as of March 31,

2016. We primarily finance our operations through the sale of equity securities, licensing fees, royalties on product sales by our licensees, research grants, subscription fees and advertising revenue from database products. Ultimately, our ability to generate sufficient operating revenue to earn a profit depends upon our success in developing and marketing or licensing our product candidates. If we are unable to do so, our results of operations will be materially harmed and the value of our common stock could decrease.

***We need to spend a substantial amount of our capital on research and development but we might not succeed in developing products and technologies that are accepted by the market.***

We are developing new medical products and technologies. Many of our product candidates 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.

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Our development efforts are costly, time consuming, and uncertain as to their results. We incurred research and development expenses of \$42.6 million, \$37.5 million, and \$26.6 million during the fiscal years ended December 31, 2015, 2014, and 2013, respectively, excluding \$17.5 million charged as acquired in process research and development expenses during 2013 in connection with Asterias' acquisition of certain assets from Geron Corporation, or Geron. 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, particularly those products that are regulated as drugs or biological, 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.

***We will 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 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.

Our ability, and the ability of our subsidiaries, to raise additional equity or debt capital will depend not only on progress made in developing new products and technologies, but also will depend on access to capital and conditions in the capital markets. We may not be able to raise capital at times and in amounts needed to finance product development, clinical trials, and general operations. Even if capital is available, it may not be available on terms that we or our shareholders would consider favorable. Sales of additional equity securities could result in the substantial dilution for our shareholders. If we were to incur debt to finance our operations, it could have restrictions on our business operations.

***The operations of OncoCyte Corporation, or OncoCyte, could result in an increase in our operating expenses and losses on a consolidated basis.***

While we no longer are required to consolidate our operations with that of Asterias, we are still required to consolidate our operations with OncoCyte. The expansion of OncoCyte will involve substantial expense, including but not limited to hiring additional research and management personnel, and marketing personnel if it successfully completes the development of its initial cancer diagnostic tests, and those expenses will add to our losses on a consolidated basis for the near future. OncoCyte is public company and will incur costs associated with audits of its financial statements, filing annual, quarterly, and other periodic reports with the SEC, holding annual shareholder meetings, listing their common stock for trading, and public relations and investor relations. These costs will be in addition to those incurred by us for similar purposes.

***Patents pertaining to the manufacture of retinal pigment epithelium, or RPE, products from pluripotent cells recently issued to one of our competitors and could impact the rights of Cell Cure Neurosciences Ltd., or Cell Cure Neurosciences, to manufacture and commercialize OpRegen®.***

The U.S. Patent and Trademark Office, or USPTO, issued certain RPE-related patents to Ocata Therapeutics, or Ocata, in 2015, with claims directed to methods of producing RPE cell compositions for human therapy. If the process used by Cell Cure Neurosciences to manufacture RPE cells for *OpRegen*<sup>®</sup> were to be determined to infringe the issued claims and if the patented claims were to be determined to be valid, Cell Cure Neurosciences might not be permitted to manufacture *OpRegen*<sup>®</sup> and commercialize that product in the United States or in other countries in which such patent claims may have issued.

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

The success of Ascendance Biotechnology, Inc. s, or Ascendance, 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