BIOTIME INC
Form 424B5
February 09, 2017
TABLE OF CONTENTS

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 FEBRUARY 9, 2017

PRELIMINARY PROSPECTUS SUPPLEMENT
(To Prospectus dated February 12, 2015)

Shares of 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 February 8, 2017, the last reported sale price for our common stock on the NYSE MKT was $3.01 per share.

One of our significant shareholders has indicated an interest in purchasing up to an aggregate of $ million in shares of our common stock in this offering at the offering price to the public. 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 shareholder, or the shareholder may determine to purchase more, less or no shares in this offering.

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

	Per Share	Total
Public Offering Price	$	$
Underwriting discounts and commissions[1]	$	$
Proceeds to us, before expenses	$	$

(1) We have also agreed to reimburse the underwriters for certain of their expenses. See Underwriting on page S-30 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 any. 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 February , 2017.

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

RAYMOND JAMES

The date of this prospectus supplement is February , 2017

TABLE OF CONTENTS

TABLE OF CONTENTS

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.

TABLE OF CONTENTS

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.

TABLE OF CONTENTS

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 its consolidated 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 its consolidated 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 pluripotent cell technology and a three dimensional cell delivery matrix technology for the delivery and engraftment of such cells. Currently, we and our subsidiaries and affiliates have five such therapies in human clinical trials (as discussed below, *Renevia*®, *OpRegen*®, *AST-OPC1, AST-VAC1 and AST-VAC 2*), including one that is in a pivotal study in Europe from which data are expected in the second quarter of 2017. 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 cell technology is complemented by our *HyStem*® hydrogel technology for the delivery and engraftment of cells, whether derived from pluripotent stem cells or the patient s own somatic or adult stem cells, at the desired location. This technology has potential therapeutic applications as a volumizer in cosmetic procedures, and to provide a matrix for the administration of therapeutic cells or biologics to a patient. *HyStem*® is the underlying technology for our *Renevia*® product currently undergoing a pivotal clinical trial for the treatment of HIV-related lipoatrophy. *HyStem*® hydrogels use naturally-occurring components such as hyaluronan and collagen with a proprietary cross-linker to mimic the natural environment that cells experience in the body, called the extracellular matrix, to create three-dimensional tissue.

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, especially during the early stages of development for therapeutic and non-therapeutic product lines, as compared to strategies commonly deployed by other companies in the biotechnology industry. As a result, we, with our subsidiaries and affiliates, have been able to develop multiple clinical-stage products rather than being dependent on a single product program. We and some of our subsidiaries and affiliates 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.

More recently, as many of our programs are maturing, we have focused on simplifying our business, focusing on therapeutic development programs and increasing transparency. Simplification of our corporate structure and operations is important as it helps us focus on our high-priority activities, especially candidates in human clinical development. Simplification also helps us communicate more effectively to prospective investors, analysts and partners. Asterias Biotherapeutics, Inc., or Asterias, (NYSE MKT: AST), an affiliate of our company, and OncoCyte Corporation, or OncoCyte, (NYSE MKT: OCX), one of our subsidiaries, have evolved into publicly traded companies with shares traded on the NYSE MKT.

As of September 30, 2016, we held, directly and indirectly through subsidiaries, affiliates and equity method investments, interests in 10 operating entities located throughout the world. In the United States, we own

TABLE OF CONTENTS

interests in Ascendance Biotechnology, Inc., or Ascendance, Asterias, LifeMap Sciences, Inc., or LifeMap Sciences, LifeMap Solutions, Inc., or LifeMap Solutions, OncoCyte, OrthoCyte Corporation, or OrthoCyte, and ReCyte Therapeutics, Inc., or ReCyte.

We hold an approximately 46% interest in Ascendance, a company that manufactures and sells proprietary products and services that assay new drug candidates for potential toxicity, including *HepatoPac*® and *HepatoMune*®, and other products for use as research tools by a range of customers, including several leading global pharmaceutical companies. We hold an approximately 45% 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 myeloid leukemia, or AML, and AST-VAC2 for non-small cell lung cancer. We hold an approximately 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.

We hold an approximately 51% 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 approximately 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 approximately 62.5% 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*®, which is a potential therapy derived from National Institutes of Health-registered pluripotent human stem cells for the treatment of the dry form of AMD. Cell Cure Neuorsciences manufactures *OpRegen*® under fully scalable Current Good Manufacturing Practice conditions. Patients are currently being treated with *OpRegen*® in a Phase I/IIa dose-escalation clinical trial. We expect to complete enrollment of the second cohort of this trial and receive clearance from the independent Data and Safety Monitoring Board, or DSMB, and to begin and complete enrollment in the third cohort in the first half of 2017. We expect to report six-month data from the second cohort of this trial and clearance from the DSMB to begin the fourth cohort in the second half of 2017. In addition, we expect to report completion of the first cohort of this trial, the second cohort is expected to be enrolled and we anticipate approval from the DSMB to proceed to the third cohort, by the end of this year

In addition, we are currently developing *Renevia*® as a potential treatment for HIV related facial lipoatrophy, a syndrome that occurs in HIV-infected patients who are being treated with antiretroviral medications. *Renevia*® consists of our proprietary cell-transplantation delivery matrix, *HyStem*®, combined with the patient s own adipose

cells. Approximately 350,000 people in Europe have HIV-related lipoatrophy or facial wasting. We plan to file our CE Mark in Europe in the second half of 2017. In addition, we intend to complete enrollment for a pivotal trial in the United States and initiate that trial during the first half of 2017. *Renevia*® 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*® has much broader applications beyond its use in patients with HIV. It is estimated that the global facial aesthetics

TABLE OF CONTENTS

market was valued at $2.5 billion in 2013 and is expected to reach $5.4 billion by 2020. We believe there are approximately 460,000 procedures per year in which *Renevia*® could possibly be utilized apart from the current developed use as a potential treatment for HIV related facial lipoatrophy. In addition, in 2014 there were approximately 1 million augmentation or reconstruction surgical procedures performed in the United States. Such procedures include approximately 70,000 reimbursed facial fat transfer procedures and an estimated 500,000 cash pay 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*® 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*® 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 and affiliates, we are advancing two late-stage pivotal trials and a robust pipeline which includes the following programs:

- *OpRegen*® is in a Phase I/IIa clinical trial to treat the dry form of AMD.
- *Renevia*® is currently in a Phase III 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. We expect this trial to be completed in the first half of 2017. *Renevia*® has the potential to obtain regulatory approval in Europe in the second half of 2017. If the clinical trial proceeds as anticipated, we may commence trials in another major world market, such as South Korea, China or the United States.
- 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. OncoCyte expects to complete a 300-patient study analysis for its lung cancer assay in the first half of 2017 and its breast cancer assay in the second half of 2017.
- AST-OPC1, a potential therapy derived from pluripotent stem cells, is in a Phase I/IIa trial for spinal cord injury rehabilitation. We anticipate six and nine-month data from the second cohort of the American Spinal Injury Association, or ASIA, Classification A trial in the first half of 2017, and the six and twelve-month data from the ASIA-Classification B first cohort in the second half of 2017. AST-VAC2 is advancing toward clinical development for non-small cell lung cancer, both pluripotent stem cell-based therapies being developed by Asterias.
- Our collaborator, Cancer Research UK, is preparing to initiate a Phase I/II clinical trial of AST-VAC2 for the first quarter of 2017 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 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.
- 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*®, 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.

S-3

TABLE OF CONTENTS

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. 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.

TABLE OF CONTENTS

THE OFFERING

Shares of common stock offered
Shares
Underwriters over allotment option
Shares
Offering Price
$
Shares of common stock to be outstanding after this offering
Shares (or shares if the underwriters over allotment option is exercised in full)
Use of proceeds
We intend to use the net proceeds from this offering for general corporate purposes, including, without limitation, to fund clinical trials, research and development activities and for general working capital. See Use of Proceeds on page S-27.
Risk factors
See Risk Factors beginning S-6 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 102,772,542 shares of common stock issued and outstanding as of September 30, 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 6,497,105 shares of common stock, with a weighted average exercise price of $3.61 per share;
- 100,000 restricted stock units issued to certain executives under our 2012 Equity Incentive Plan; and
- 3,516,000 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 over allotment option.

TABLE OF CONTENTS

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 6 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 U.S. Securities and Exchange Commission, or 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 fund 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 affiliates, or in any new subsidiaries that we may form, or new entities we may become affiliated with. 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 operating losses for the nine months ended September 30, 2016 and for the fiscal years ended December 31, 2015 and 2014, were $47.7 million, $65.8 million and $50.7 million, respectively, and we had an accumulated deficit of

$190.5 million as of September 30, 2016. Our comprehensive income for the nine months ended September 30, 2016 was $25.9 million and comprehensive loss for the nine months ended September 30, 2015 was $41.6 million. For the fiscal years ended December 31, 2015, 2014 and 2013, our total comprehensive losses were $58.6 million, $43.7 million and $52.8 million, respectively. 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.

TABLE OF CONTENTS

We will spend a substantial amount of our capital on research and development activities 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. Some 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 of $29.1 million during the nine months ended September 30, 2016, and $42.6 million and $37.5 million during the fiscal years ended December 31, 2015 and 2014, 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, 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.

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

At September 30, 2016, we had $30.5 million of cash and cash equivalents on hand, of which $15.0 million was held by our subsidiaries. On June 21, 2016 and July 5, 2016, we completed an underwritten public offering to issue 7,322,176 shares of our common stock including the full exercise of the over allotment by the underwriters of 1,098,326 shares of our common stock, raising net proceeds of approximately $18.6 million after underwriting discounts and other expenses. We and our subsidiaries may not be able to raise additional funds on favorable terms or at all, and any funds raised may not be sufficient to permit us or our subsidiaries and affiliates to develop and market our products and technologies. Unless we and our subsidiaries and affiliates 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 may have to postpone or limit the pace of our research and development work and planned clinical trials of our product candidates unless our cash resources increase through a growth in revenues or additional equity investment or borrowing.

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 and affiliates 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 and affiliates, 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 Biotherapeutics, Inc., or Asterias, we are still required to consolidate our operations with OncoCyte. The expansion of OncoCyte will

TABLE OF CONTENTS

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 a 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 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 in 2015, which has since been indirectly acquired by Astellas Pharma Inc., 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®* 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®* and commercialize that product in the United States or in other countries in which such patent claims may have been 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 small market for our products and technologies. 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 therapeutic products.

The growth in stem cell research also depends upon the availability of funding through private investment and government research grants. In the event of a failed trial of a proposed stem cell product by us or by another company, for reasons of efficacy or safety, it could be increasingly difficult to secure funding or develop adequate supporting data to enable the submission of future investigational new drug applications, or INDs, to the FDA.

Safe and clinically effective human medical applications may not be developed using stem cells or related technology. If serious adverse events related to cell therapy products were to arise in clinical trials or after marketing approval, the FDA or foreign regulators could impose more restrictive safety requirements on cell therapy products generally, including in the manner of use and manufacture, could require safety warnings in product labeling, and could limit, restrict or deny permission for new cell therapy products to enter clinical trials or to be marketed or withdraw previously granted approvals.

We are providing funding for the development of new software products.

Our subsidiary, LifeMap Sciences, Inc., or LifeMap Sciences, has formed a new subsidiary, LifeMap Solutions, Inc., or LifeMap Solutions, to develop new personal mobile health software products intended to connect users with their complex personal health information and other big data. The field of mobile health products, including both hardware and software products, is new, and LifeMap Solutions may not be successful in developing its planned new products or in commercializing any products that it does develop.

LifeMap Solutions has not yet launched any commercial products, and we would need to continue to provide funding for the development and commercialization of the planned products, unless it is able to obtain financing from other sources. The field of mobile health products is subject to increasing competition, including from large computer and

internet technology companies that have much greater financial and marketing resources than we and LifeMap Solutions have.

The FDA has also taken an interest in the field of on-line or mobile health products and there is a risk that the FDA could determine that LifeMap Solutions products should be regulated as medical devices under existing laws and regulations, or the FDA could promulgate new regulations that might subject LifeMap Solutions products to FDA clinical trial and approval procedures, as a prerequisite for permission to use and market the new mobile health products in the United States. Foreign regulatory authorities could make similar determinations or could adopt their own rules regulating the use and marketing of LifeMap Solution s products.

TABLE OF CONTENTS

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

The biotechnology industry is intensely competitive and any therapies developed by us or our subsidiaries would compete with existing therapies or therapies in development. There are many biotechnology companies, public and private universities, government agencies and research organizations that compete with us in developing various approaches to therapies in the field of regenerative medicine. Moreover, other companies are also working on the development of stem cell based therapies for the same diseases and disorders that are the focus of the research and development programs of our subsidiaries. Some or all of these companies may have greater financial resources, larger technical staffs and larger research budgets than we have, as well as greater experience in developing products and running clinical trials. We expect to continue to experience significant and increasing levels of competition in the future.

Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors. In order to compete with other products, particularly those that sell at lower prices, our products will have to provide medically significant advantages. 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. If such products are proven to be safe and effective, they may reach the market ahead of our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Sales of Hextend® have been adversely affected by safety and use labeling changes required by the FDA.

Sales of *Hextend®* have been adversely affected by certain safety labeling changes required by the FDA for the entire class of hydroxyethyl starch products, including *Hextend®*. The labeling changes were approved by the FDA in November 2013 and include a boxed warning stating that the use of hydroxyethyl starch products, including *Hextend®*, increases the risk of mortality and renal injury requiring renal replacement therapy in critically ill adult patients, including patients with sepsis, and that *Hextend®* should not be used in critically ill adult patients, including patients with sepsis. New warning and precaution information is also required along with new information about contraindications, adverse reactions, and information about certain recent studies. The new warning and precautions include statements to the effect that the use of *Hextend®* should be avoided in patients with pre-existing renal dysfunction, and the coagulation status of patients undergoing open heart surgery in association with cardiopulmonary bypass should be monitored as excess bleeding has been reported with hydroxyethyl starch solutions in that population and use of *Hextend®* should be discontinued at the first sign of coagulopathy. The liver function of patients receiving hydroxyethyl starch products, including *Hextend®* should also be monitored. The approved revised label may adversely affect *Hextend®* sales since some users of plasma volume expanders might elect to abandon the use of all hydroxyethyl starch products, including *Hextend®*.

Any cell-based products that receive regulatory approval may be difficult and expensive to manufacture on a commercial scale.

Pluripotent stem derived therapeutic cells have only been produced on a small scale and not in quantities and at levels of purity and viability that will be needed for wide scale commercialization. If we are successful in developing products that consist of pluripotent stem cells or other cells or products derived from pluripotent stem or other cells, we will need to develop, alone or in collaboration with one or more pharmaceutical companies or contract manufacturers, technology for the commercial production of those products.

Pluripotent stem cell or other cell based products are likely to be more expensive to manufacture on a commercial scale than most other drugs on the market today. The high cost of manufacturing a product will require that we charge our customers a high price for the product in order to cover our costs and earn a profit. If the price of our products is too high, hospitals and physicians may be reluctant to purchase our products, especially if lower priced alternative products are available, and we may not be able to sell our products in sufficient volumes to recover our costs of development and manufacture or to earn a profit.

TABLE OF CONTENTS

We and our subsidiaries and affiliates will have certain obligations and may incur liabilities arising from clinical trials, and we do not yet know the scope of any resulting expenses that might arise.

We or our subsidiaries and affiliates that conduct clinical trials of product candidates face the risk of incurring liabilities to patients if they incur any injuries as a result of their participation in the clinical trials. We or our subsidiaries and affiliates will also be obligated to obtain information and prepare reports about the health of the clinical trial patients. In addition, Asterias has assumed Geron s obligations to obtain information and prepare reports about the health of patients, and has assumed any liabilities to those patients that might arise from any injuries they may have incurred, as a result of their participation in the clinical trials of Geron s GRN-OPC1 cell replacement therapy for spinal cord damage and its GRN-VAC1 immunological therapy for certain cancers. We are not aware of any claims by patients alleging injuries suffered as a result of any of our clinical trials or the Geron clinical trials, but if any claims are made and if liability can be established, the amount of any liability that we or our subsidiaries and affiliates may incur, depending upon the nature and extent of any provable injuries, could exceed any insurance coverage that we or our subsidiaries and affiliates may obtain, and the amount of the liability could be material to our financial condition.

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

Our stem cell research programs, and to a lesser extent, the programs of our subsidiaries, are directed primarily by our Co-Chief Executive Officers, Dr. Michael West and Adi Mohanty. Our subsidiaries and affiliates are directed by their respective management teams. The loss of the services of Dr. West, Mr. Mohanty or other members of senior management of us or of our subsidiaries and affiliates could have a material adverse effect on us.

If we make strategic acquisitions, we will incur a variety of costs and might never realize the anticipated benefits.

We may attempt to acquire approved products, additional drug candidates, diagnostic tests, technologies, or businesses that we believe are a strategic fit with our business. If we pursue any transaction of that sort, the process of negotiating the acquisition and integrating an acquired product, drug candidate, diagnostic test, technology, or business might result in operating difficulties and expenditures and might require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. Moreover, we might never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities, or impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition.

We may experience losses due to product liability claims, product recalls or corrections.

The design, development, manufacture and sale of medical products involve an inherent risk of product liability or other claims by patients and other third parties. The pharmaceutical and cell-based products, medical devices, and diagnostic tests that we license or acquire may cause, or may appear to cause, serious adverse side effects or potentially dangerous drug interactions if misused, improperly prescribed, improperly implanted or subject to faulty surgical technique. While we carry product liability insurance, which includes coverage for ongoing and future clinical trials we conduct, this insurance may not be sufficient to cover all claims. Insurance coverage is expensive and may be difficult to obtain. If we become liable for any product liability claims in excess of coverage or outside of coverage, the cost and expense of such liability could cause earnings and financial condition to suffer, which could lead to losses for us.

The FDA and similar foreign governmental authorities have the authority to require the recall of certain types of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the

FDA regulation of devices, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers of any FDA-regulated product may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or our licensors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and could adversely affect our business.

TABLE OF CONTENTS

Failure of our internal control over financial reporting could harm our business and financial results.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of the financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Our growth and entry into new products, technologies and markets will place significant additional pressure on our system of internal control over financial reporting. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud.

Operating our business through subsidiaries, some of which are located in foreign countries, also adds to the complexity of our internal control over financial reporting and adds to the risk of a system failure, an undetected improper use or expenditure of funds or other resources by a subsidiary, or a failure to properly report a transaction or financial results of a subsidiary. We allocate certain expenses among us and one or more of our subsidiaries, which creates a risk that the allocations we make may not accurately reflect the benefit of an expenditure or use of financial or other resources by us as the parent company and the subsidiaries among which the allocations are made. An inaccurate allocation may impact our consolidated financial results, particularly in the case of subsidiaries that we do not wholly own since our financial statements include adjustments to reflect the minority ownership interests in our subsidiaries held by others.

We are exposed to risks related to our international operations and failure to manage these risks may adversely affect our operating results and financial condition.

Through our subsidiaries and affiliates, we have operations both inside and outside the United States, and we expect to expand our international operations in the future. We may, therefore, be denied access to our customers or suppliers or denied the ability to ship any acquired product, drug candidate, diagnostic test, technology, or business products as a result of a closing of the borders of the countries in which our operations are located, due to economic, legislative, political and military conditions in such countries.

International operations are subject to a number of other inherent risks, and our future results could be adversely affected by a number of factors, including:

- differing existing or future regulatory and certification requirements;
- management communication and integration problems resulting from cultural and geographic dispersion;
- greater difficulty in collecting accounts receivable and longer collection periods;
- difficulties and costs of staffing and managing non-U.S. operations;
- the uncertainty of protection for intellectual property rights in some countries;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell potential products;
- more stringent data protection standards in some countries;
- greater risk of a failure of foreign employees to comply with both U.S. and foreign laws, including export and antitrust regulations, the U.S. Foreign Corrupt Practices Act and any trade regulations ensuring fair trade

practices;

- heightened risk of unfair or corrupt business practices in certain geographies and of improper or fraudulent sales arrangements that may impact financial results and result in restatements of, or irregularities in, financial statements;

TABLE OF CONTENTS

- foreign currency exchange rates;
- potentially adverse tax consequences, including multiple and possibly overlapping tax structures; and
- political and economic instability, political unrest and terrorism.

Our multi-subsidiary corporate structure may give rise to administrative inefficiencies and may add to our administrative expenses.

The operation of our business through multiple subsidiaries will result in certain administrative expense that we would not incur if all of our operations were conducted within our company itself. Our subsidiaries generally provide compensation to their own executive management teams and members of their boards of directors who are not employees of us or of one of our subsidiaries. Other expenses arise from more complex record keeping and internal procedures for allocating various operating expenses, such as rent, equipment, utilities, and shared personnel, among us and our subsidiaries, and from the obligations of OncoCyte to prepare and file its own periodic financial and informational reports and proxy materials with the SEC and to hold annual meetings of its shareholders.

We may also face conflicts of interest in managing, financing, engaging in transactions with, or allocating business opportunities to, subsidiaries that are not wholly-owned by us. Our directors and those of our subsidiaries will consider their fiduciary duties to us and our subsidiaries, and in certain circumstances decisions making may be delegated to committees of directors who are independent under the rules of the NYSE MKT. We or our subsidiaries also may engage the services of independent financial advisers to provide valuations and other advice with respect to certain proposed transactions.

Our business and operations could suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of data for our product candidates could result in delays in our regulatory filings and development efforts and significantly increase our costs. To the extent that any disruption or security breach was to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes and ownership change, generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. As of December 31, 2015, we had $166.1 million and $105.3 million of federal and state NOLs, respectively, available to offset our future taxable income, if any. In addition, as of December 31, 2015, we had research tax credit carryforwards for federal and state tax purposes of $4.1 million and $4.2 million, respectively. The federal tax credits expire between 2018 and 2035, while the state tax credits have no expiration date. As of December 31, 2015, our subsidiaries have foreign net operating loss carryforwards of approximately $59.7 million which carry forward indefinitely. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Our ownership interest in several of our operating subsidiaries is less than 100% and may fluctuate over time, and shares in our subsidiaries may be sold to third parties at the discretion of management of each of those subsidiaries.

As of September 30, 2016, we held, directly and indirectly through subsidiaries, interests in 10 operating entities located throughout the world. Our ownership interest in several of our operating subsidiaries is less than 100%. Any issuance of shares of a subsidiary to third parties is at the discretion of management of that subsidiary and may dilute our percentage ownership in that subsidiary and our proportionate right to any dividends paid by that subsidiary or any net gain on the occurrence of any liquidation event. In addition, if our percentage ownership

TABLE OF CONTENTS

drops to too low a level, we may have difficulty controlling the operations of the subsidiary or controlling it in circumstances where law or operative agreements require a majority or super-majority vote of stockholders in order to exercise control. In addition, in circumstances where we control a subsidiary, to the extent there are minority investors in the subsidiary we owe them various duties of fair dealing under applicable state laws, and they may be able to take the subsidiary to court or seek to be bought out of their investments at prices favorable to them if they are sufficiently dissatisfied with our control of the subsidiary. If we are unable to adequately manage the capital structure of our subsidiaries, our operations and results may be substantially affected. In addition, we may transfer shares in our subsidiaries to third parties if and when we determine that the benefits to us as a whole from such transfer outweighs the considerations against reducing our ownership in our subsidiaries.

The value of the equity we hold in Asterias and OncoCyte, both of which are publicly traded companies, is dependent on various factors, many of which are beyond our control.

We hold an approximately 45% interest in Asterias, and an approximately 51% interest in OncoCyte. As of February 6, 2017, the value of our equity ownership interest in Asterias was approximately $82 million, and the value of our equity ownership interest in OncoCyte was approximately $80 million. As publicly traded companies, the value of our equity can be volatile and is dependent upon many of the same factors that impact the trading price of our common stock. Historically, the prices of our common stock and the prices of the Asterias and OncoCyte common stock are independent. We do not control the operations of either company and are unable to take any actions that we believe may increase the trading price of their common stock. As a result, the value of our equity holdings is dependent on the success of each company s management team in executing their respective business plans and the market s perception of their success as well as other general factors impacting the biotechnology industry and the overall financial markets.

Risks Related to Our Industry

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

The therapeutic and medical device products that we and our subsidiaries develop cannot be sold until the 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 could exceed our financial resources.
- Clinical trials and the regulatory approval process for a pharmaceutical or cell-based product can take several years to complete. As a result, 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.
- 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 product may be encountered as a result of changes in regulatory agency policy.
- Because the therapeutic products we are developing with pluripotent stem cell 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.

We may not receive the necessary clearances or approvals for our future products, and failure to timely obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Our *Renevia*® product candidate may require premarket approval, or PMA, before it could be sold in the United States. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended

TABLE OF CONTENTS

use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

In addition, modifications to products that are approved through a PMA application generally require FDA approval. The PMA approval process can be expensive, lengthy and uncertain. The process of obtaining a PMA can be costly and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development or impact our ability to modify our currently cleared product on a timely basis.

Obtaining Fast Track designation from the FDA for Cell Cure Neurosciences product candidate OpRegen® does not guarantee faster approval.

Cell Cure Neurosciences received Fast Track designation from the FDA for *OpRegen®* for the treatment of dry-AMD. Fast Track designation is a process designed to facilitate the development and expedite the review of new drugs intended to treat serious or life-threatening diseases or conditions and that have the potential to address an unmet medical need for such disease or condition. Fast Track designation applies to the product and the specific indication for which it is being studied. Once a Fast Track designation is obtained, the FDA may consider for review on a rolling basis sections of the NDA before the complete application is submitted if the applicant provides and the FDA approves a schedule for the submission of the sections of the NDA and the applicant pays applicable user fees upon submission of the first section of the NDA. However, the time period specified in the Prescription Drug User Fee Act, which governs the time period goals the FDA has committed to reviewing an application, does not begin until the complete application is accepted for filing. Although Cell Cure Neurosciences received Fast Track designation for *OpRegen®* for the treatment of dry-AMD, the FDA may later decide that *OpRegen®* no longer meets the conditions for qualification. In addition, Fast Track designation may not provide us with a material commercial advantage.

Clinical trial failures can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future product candidates.

Clinical trial failures or delays can occur at any stage of the trials, and may be directly or indirectly caused by a variety of factors, including but not limited to:

- delays in securing clinical investigators or trial sites for our clinical trials;
- delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;
- slower than anticipated rates of patient recruitment and enrollment, or failing to reach the targeted number of patients due to competition for patients from other trials;
- limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payors for the use of agents used in our clinical trials;
- negative or inconclusive results from clinical trials;
- unforeseen side effects interrupting, delaying or halting clinical trials of our product candidates and possibly resulting in the FDA or other regulatory authorities denying approval of our product candidates;
- unforeseen safety issues;

- uncertain dosing issues;

TABLE OF CONTENTS

- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unavailability of clinical trial supplies.

Government-imposed bans or 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 bans or restrictions on the use of embryos or hES cells in research and development 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 review oversight committee, or 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.

In addition to interference proceedings, the USPTO 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. Our patents may be subject

to *inter partes* review (replacing the prior *inter partes* reexamination proceeding), a proceeding in which a third party can challenge the validity of one of our patents.

TABLE OF CONTENTS

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, 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, may not result in the issuance of patents.

In Europe, there is uncertainty about the eligibility of hES cell subject matter for patent protection. The European Patent Convention prohibits the granting of European patents for inventions that concern uses of human embryos for industrial or commercial purposes. A recent decision at the Court of Justice of the European Union interpreted parthenogeneticly produced hES cells as patentable subject matter. Consequently, the European Patent Office now recognizes that human pluripotent stem cells (including human ES cells) can be created without a destructive use of human embryos as of June 5, 2003, and patent applications relating to hES cell subject matter with a filing and priority date after this date are no longer automatically excluded from patentability under Article 53 (a) EPC and Rule 28(c) EPC.

The Supreme Court decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics* will need to be considered in determining whether certain diagnostic methods and reagents can be patented, since the Court denied patent protection for the use of a mathematical correlation of the presence of a well-known naturally occurring metabolite as a means of determining proper drug dosage, and found that DNA sequences isolated from humans were not patent eligible. Our subsidiary OncoCyte is developing cancer diagnostic tests based on the presence of certain genetic markers and proteins for a variety of cancers. Because OncoCyte s planned diagnostic tests combine an innovative methodology with newly discovered compositions of matter, we are hopeful that the Supreme Court decision will not preclude the availability of patent protection for the diagnostic tests that OncoCyte is developing. However, like other developers of diagnostic products, OncoCyte is evaluating the Supreme Court decision and interim guidelines issued by the USPTO for the patenting of products that test for biological substances.

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 USPTO for patents or applications filed before March 16, 2013 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 USPTO may 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 USPTO 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.

A derivation proceeding may be instituted by the USPTO or an inventor alleging that a patent or application was derived from the work of another inventor. Post Grant Review under the new Leahy-Smith America Invents Act makes available opposition-like proceedings in the United States. As with the USPTO interference proceedings, Post Grant Review proceedings will be very expensive to contest and can result in cancellation of a patent.

Oppositions to the issuance of patents may be filed under European patent law and the patent laws of certain other countries. As with the USPTO 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.

TABLE OF CONTENTS

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, require us to pay licensing fees to have freedom to operate, and/or result in monetary damages or other liability for us.

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 and diagnostic tests may be limited by health insurance coverage and government regulation.

Success in selling our pharmaceutical and cell-based products, medical devices, and diagnostic tests 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, tests, and related treatment. Presently, most health insurance plans and HMOs will pay for *Hextend*® when it is used in a surgical procedure that is covered by the plan. However, until we actually introduce a new product or diagnostic test into the medical marketplace, we will not know with certainty whether adequate health insurance, HMO, and government coverage will be available to permit the product or test to be sold at a price high enough for us to generate a profit. In some foreign countries, pricing or profitability of health care products is subject to government control, which may result in low prices for our products. In the United States, there have been a number of federal and state proposals to implement similar government controls, and new proposals are likely to be made in the future.

The continued implementation of, or the possible repeal and replacement of, the Patient Protection and Affordable Care Act, or ACA, in the United States may adversely affect our business.

As a result of the adoption of the ACA in the United States, substantial changes are being made to the current system for paying for healthcare in the United States, including programs to extend medical benefits to millions of individuals who currently lack insurance coverage. The changes contemplated by the ACA are subject to rule-making and

implementation timelines that extend for several years, as well as initiatives in Congress to amend or repeal the law, and this uncertainty limits our ability to forecast changes that may occur in the future. However, implementation of the ACA has already begun with respect to certain significant cost-saving measures, including changes to several government healthcare programs that may cover the cost of our future products and diagnostic tests, including Medicaid, Medicare Parts B and D, and these efforts could have a materially adverse impact on our future financial prospects and performance. For example, with respect to Medicaid, in order for a manufacturer s products to be reimbursed by federal funding under Medicaid, the manufacturer must enter into a Medicaid rebate agreement with the Secretary of the United States Department of Health and Human Services, and must pay certain rebates to the states based on utilization data provided by each state to the manufacturer

TABLE OF CONTENTS

and to the Centers for Medicare and Medicaid Services, or CMS, and based on pricing data provided by the manufacturer to the federal government. The states share this savings with the federal government, and sometimes implement their own additional supplemental rebate programs. Under the Medicaid drug rebate program, the rebate amount for most branded drug products was previously equal to a minimum of 15.1% of the Average Manufacturer Price, or AMP, or the AMP less Best Price, whichever is greater. Effective January 1, 2010, the ACA generally increased the size of the Medicaid rebates paid by manufacturers for single source and innovator multiple source (brand name) drug product from a minimum of 15.1% to a minimum of 23.1% of the AMP, subject to certain exceptions, for example, for certain clotting factors, the increase is limited to a minimum of 17.1% of the AMP. For non-innovator multiple source (generic) products, the rebate percentage is increased from a minimum of 11.0% to a minimum of 13.0% of AMP. These increases in required rebates may adversely affect our future financial prospects and performance. The ACA also creates new rebate obligations for products under Medicare Part D, a partial, voluntary prescription drug benefit created by the United States federal government primarily for persons 65 years old and over. The Part D drug program is administered through private insurers that contract with CMS. Beginning in 2011, the healthcare reform law generally requires that in order for a drug manufacturer s products to be reimbursed under Medicare Part D, the manufacturer must enter into a Medicare Coverage Gap Discount Program agreement with the Secretary of the United States Department of Health and Human Services, and reimburse each Medicare Part D plan sponsor an amount equal to 50% savings for the manufacturer s brand name drugs and biologics which the Part D plan sponsor has provided to its Medicare Part D beneficiaries who are in the donut hole (or a gap in Medicare Part D coverage for beneficiaries who have expended certain amounts for drugs). The Part D plan sponsor is responsible for calculating and providing the discount directly to its beneficiaries and for reporting these amounts paid to CMS s contractor, which notifies drug manufacturers of the rebate amounts it must pay to each Part D plan sponsor. The rebate requirement could adversely affect our future financial performance, particularly if contracts with Part D plans cannot be favorably renegotiated or the Part D plan sponsors fail to accurately calculate payments due in a manner that overstates our rebate obligation.

The ACA also introduced an abbreviated pathway for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-licensed biological product, or the reference product. The new law provides that a biosimilar application may be submitted as soon as four years after the reference product is first licensed, and that the FDA may not make approval of an application effective until 12 years after the reference product was first licensed. With the likely introduction of biosimilars in the United States, we expect in the future to face greater competition from biosimilar products for any of our biologic products for which we receive approval, including a possible increase in patent challenges. The FDA has already approved several biosimilar products, and is continuing to provide guidance regarding the abbreviated regulatory review pathway. Regarding access to our products, the ACA established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research, or CER. While the stated intent of CER is to develop information to guide providers to the most efficacious therapies, outcomes of CER could influence the reimbursement or coverage for therapies that are determined to be less cost-effective than others. Should any of our products be determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our future financial prospects and results.

CMS recently proposed a new plan to alter Medicare Part B, which pays for medications administered in doctors officers or outpatient hospital clinics. The new plan aims to eliminate incentives for doctors to use the most expensive drugs. Under the current plan, Medicare Part B reimburses doctors or clinics for the cost of the medication plus a 6% fee. CMS plans to test a reimbursement formula that would pay the cost of the drug, plus a 2.5% surcharge and a flat fee of $16.80. CMS hopes that the proposed plan would cut costs by eliminating incentives to choose high priced drugs over ones that may be more appropriate. CMS is planning to test various value-based pricing ideas that would pay for drugs according how well they work. For example, if a medication is effective in eliminating one condition but is also used on a second condition with less success, Medicare would pay less when it is used for the second condition than the first. Certain private health insurance plans are also implementing similar new reimbursement procedures for

physicians administered medications that will base reimbursements on the effectiveness of the selected drug. CMS proposed plans are open for public comment until May 9, 2016, and field tests will begin upon completion of the comment period. While the ultimate adoption of the proposals is uncertain, if adopted, the plans could affect doctors utilization of any therapeutic products that we may successfully develop.

TABLE OF CONTENTS

President Trump ran for office on a platform that supported the repeal of the ACA and one of his first actions after his inauguration was to sign an Executive Order commanding federal agencies to try to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. The Order also declares that the administration will seek the prompt repeal of the law and that the government should prepare to afford the states more flexibility and control to create a more free and open healthcare market. At this time, it is not clear whether the ACA will be repealed in its entirety, whether it will be replaced in whole or in part by another plan. and what impact those changes will have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and also indirectly affect the amounts that private payors are willing to pay. These changes could result in reduced demand for our product candidates once approved or additional pricing pressures, and may adversely affect our operating results.

Risks Related to our Dependence on Third Parties

Asterias could lose its grant from the California Institute of Regenerative Medicine, or CIRM, if Asterias fails to meet the clinical trial milestones that are a condition to CIRM s obligation to provide funding.

Asterias depends on its grant from CIRM as a source of financing for the costs of conducting its Phase I/IIa clinical trial and process development of AST-OPC1. Under the terms of the CIRM grant, Asterias must meet certain efficacy and progress milestones pertaining to the clinical trial. If Asterias fails to meet any of the milestones within the specified time frame, CIRM may discontinue providing grant funds to Asterias, which could force Asterias to postpone, delay, or discontinue the clinical trial and development work for the product.

If we fail to enter into and maintain successful strategic alliances for our therapeutic product candidates, we may have to reduce or delay our product development or increase our expenditures.

An important element of our strategy for developing, manufacturing and commercializing our therapeutic product candidates will be entering into strategic alliances with pharmaceutical companies or other industry participants to advance our programs and enable us to maintain our financial and operational capacity. We will face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our product development or research programs, or we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

If we are able to enter into product development and marketing arrangements with pharmaceutical companies, we may license product development, manufacturing, and marketing rights to the pharmaceutical company or to a joint venture company formed with the pharmaceutical company. Under such arrangements we might receive only a royalty on sales of the products developed or an equity interest in a joint venture company that develops the product. As a result, our revenues from the sale of those products may be substantially less than the amount of revenues and gross profits that we might receive if we were to develop, manufacture, and market the products ourselves.

We may become dependent on possible future collaborations to develop and commercialize many of our product candidates and to provide the regulatory compliance, sales, marketing and distribution capabilities required for the success of our business.

We may enter into various kinds of collaborative research and development and product marketing agreements to develop and commercialize our products. The expected future milestone payments and cost reimbursements from collaboration agreements could provide an important source of financing for our research and development programs,

thereby facilitating the application of our technology to the development and commercialization of our products, but there are risks associated with entering into collaboration arrangements.

There is a risk that we could become dependent upon one or more collaborative arrangements. A collaborative arrangement upon which we might depend might be terminated by our collaboration partner or a partner might determine not to actively pursue the development or commercialization of our products. A collaboration partner also may not be precluded from independently pursuing competing products and drug delivery approaches or technologies.

TABLE OF CONTENTS

There is a risk that a collaboration partner might fail to perform its obligations under the collaborative arrangements or may be slow in performing its obligations. In addition, a collaboration partner may experience financial difficulties at any time that could prevent it from having available funds to contribute to the collaboration. If a collaboration partner fails to conduct its product development, commercialization, regulatory compliance, sales and marketing or distribution activities successfully and in a timely manner, or if it terminates or materially modifies its agreements with us, the development and commercialization of one or more product candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue such development and commercialization on our own.

We have very limited experience in marketing, selling or distributing our products, and we may need to rely on marketing partners or contract sales companies.

Even if we are able to develop our products and obtain necessary regulatory approvals, we have very limited experience or capabilities in marketing, selling or distributing our products. We rely entirely on Hospira and CJ Health for the sale of *Hextend*®. Ascendance currently has only limited sales, marketing and distribution resources for selling its assay and stem cell research products, and we and our other subsidiaries have no other marketing or distribution resources for selling any of the medical devices or therapeutic products that are being developed. Accordingly, we and our subsidiaries will be dependent on our ability to build our own marketing and distribution capability for our new products, which would require the investment of significant financial and management resources, or we will need to find collaborative marketing partners or sales representatives, or wholesale distributors for the commercial sale of our products.

If we market products through arrangements with third parties, we may pay sales commissions to sales representatives or we may sell or consign products to distributors at wholesale prices. As a result, our gross profit from product sales may be lower than it would be if we were to sell our products directly to end users at retail prices through our own sales force. We may not be able to negotiate distribution or sales agreements with third parties on favorable terms to justify our investment in our products or achieve sufficient revenues to support our operations.

We do not have the ability to independently conduct clinical trials required to obtain regulatory approvals for our product candidates.

We will need to rely on third parties, such as contract research organizations, data management companies, contract clinical research associates, medical institutions, clinical investigators and contract laboratories to conduct any clinical trials that we may undertake for our products. We may also rely on third parties to assist with our preclinical development of product candidates. If we outsource clinical trial we may be unable to directly control the timing, conduct and expense of our clinical trials. If we enlist third parties to conduct clinical trials and they fail to successfully carry out their contractual duties or regulatory obligations or fail to meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Risks Related to the Asset Contribution Agreement With Geron

We could be liable to indemnify Geron from certain liabilities.

Under the Asset Contribution Agreement, or the Asset Contribution Agreement, through which Asterias acquired Geron s stem cell assets, we and Asterias have agreed to indemnify Geron from and against certain liabilities relating to (a) the distribution of shares of Asterias Series A common stock to Geron stockholders, (b) Asterias distribution of

certain of our warrants to the holders of Asterias Series A common stock, and (c) any distribution of securities by Asterias to the holders of the Asterias Series A common stock within one year following Asterias acquisition of Geron s stem cell assets. That indemnification obligation will last through the fifth anniversary of the expiration, exercise, cancellation or sale of our warrants whichever occurs first.

We and Asterias have also agreed to indemnify Geron, from and against certain expenses, losses, and liabilities arising from, among other things, breaches of our or Asterias representations, warranties and covenants under the

TABLE OF CONTENTS

Asset Contribution Agreement. The maximum damages that may be recovered by either party for a loss under this indemnification related to representations, warranties and covenants, with certain exceptions, is limited to $2,000,000.

Asterias operations may divert our management s attention away from ongoing operations and could adversely affect ongoing operations and business relationships.

Now that Asterias has acquired Geron s stem cell assets and is conducting its own research and development programs, our management will be required to provide more management attention to Asterias. The diversion of our management s attention away from our other operations could adversely affect our operations and business relationships that do not relate to Asterias.

Risks Related to OncoCyte s Business Operations

OncoCyte has determined that the initial diagnostic tests that it plans to develop and commercialize will be laboratory developed tests, or LDTs, that will be performed at a CLIA-certified clinical laboratory that OncoCyte plans to operate. The decision to develop and commercialize LDTs will give rise to certain risks related to the operation of diagnostic clinical laboratory and performing LDTs, including the following risks.

OncoCyte will need to obtain CLIA certification and regulatory approvals of its diagnostic laboratory facilities.

OncoCyte will need to receive certification for its planned clinical laboratory under the Clinical Laboratory Improvement Amendments of 1988, or CLIA. In addition to meeting federal regulatory requirements, each state has its own laboratory licensure and inspection requirements and some states require that each test offered by any laboratory to the residents of that state be approved. CLIA licensed laboratories can lose their licenses if problems arise during periodic regulatory inspections or for other reasons.

The FDA may impose additional regulations for laboratory developed tests such as the ones OncoCyte is developing.

The FDA regulates in vitro diagnostic tests as a medical device although it has exercised enforcement discretion in not actively regulating most LDTs that are designed, manufactured and used by a single CLIA–certified laboratory and that do not present what FDA considers a high risk. Over the past few years, the FDA has proposed variations of a risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs such as those OncoCyte is developing. However, the proposals were never finalized and the most recent one was withdrawn at the end of the Obama administration and replaced by a discussion paper that is not enforceable. If in the future the FDA implements new regulatory measures:

- OncoCyte may be required to obtain pre-market clearance or approval before selling its diagnostic tests;
- As a result of required FDA pre-market review, OncoCyte’s tests may not be cleared or approved on a timely basis, if at all;
- FDA labeling requirements may limit OncoCyte’s claims about its diagnostic tests, which may have a negative effect on orders from physicians;
- The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission, or filing a pre-market approval application, or PMA, with the FDA; and,
- If regulatory actions affect any of the reagents OncoCyte obtain from suppliers and use in conducting its tests, its business could be adversely affected in the form of increased costs of testing or delays, limits or prohibitions on the purchase of reagents necessary to perform its testing.

OncoCyte will depend on Medicare and a limited number of private payers for a significant portion of its revenues, and its revenues could decline if these payers fail to provide timely and adequate payment for its diagnostic tests.

OncoCyte expects that a substantial portion of the patients for whom it will perform diagnostic tests will have Medicare as their primary medical insurance. Even if OncoCyte s planned tests are otherwise successful, reimbursement for the Medicare-covered portions of its planned tests might not, without Medicare reimbursement, produce sufficient revenues to enable it to reach profitability and achieve its other commercial objectives.

TABLE OF CONTENTS

Medicare and other third-party payers have increased their efforts to control the cost, utilization, and delivery of health care services, and have undertaken measures to reduce payment rates for and decrease utilization of clinical laboratory testing. Because of the cost-trimming trends, any third-party payers that will cover and provide reimbursement for OncoCyte s diagnostic tests may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to OncoCyte. Any such action could have a negative impact on OncoCyte s revenues, which may have a material adverse effect on its financial condition, results of operations and cash flows.

Changes in healthcare laws and policies may have a material adverse effect on OncoCyte s financial condition, results of operations and cash flows.

As noted above, the ACA substantially changed the way health care is financed by both governmental and private insurers. With respect to clinical laboratories, the ACA reduced payment rates under the Medicare Clinical Laboratory Fee Schedule and established an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending if spending exceeds a target growth rate. Such provisions may negatively impact payment rates for OncoCyte s diagnostic tests.

The Protecting Access to Medicare Act of 2014, or PAMA, significantly altered the payment methodology under the Clinical Laboratory Fee Schedule that determines Medicare coverage for laboratory tests. Under PAMA, clinical laboratories are required to report test payment data for each Medicare-covered clinical diagnostic lab test and beginning in 2017, the Medicare payment rate for each clinical diagnostic lab test will be equal to the weighted median amount for the test from the most recent data collection period.

Congress has proposed on several occasions to impose a 20% coinsurance payment requirement on patients for clinical laboratory tests reimbursed under the Medicare Clinical Laboratory Fee Schedule, which would require OncoCyte to bill patients for these amounts. In the event that Congress were to ever enact such legislation, the cost of billing and collecting for OncoCyte s tests could often exceed the amount actually received from the patient.

On September 25, 2015, CMS released preliminary determinations for the calendar year 2016 for the Medicare Clinical Laboratory Fee Schedule for some test codes, including some for oncology diagnostics, as had been anticipated. These preliminary determinations were based on a cross walk approach rather than a gap-fill approach. A cross walk approach matches a new code for a diagnostic against existing codes to determine the appropriate payment rate; while a gap-fill approach looks at local pricing patterns, including charges for the tests and any discounts on charges and payments determined by other payers. At this point it is not clear what methodology CMS may use in their determinations for future diagnostics.

Beginning January 1, 2017, Medicare payment for any new advanced diagnostic test will be based on the list price or charge. After the test is commercially available for two quarters, the laboratory will be required to report payment and volume information and that data will be used to set payment for the test for the following year.

- If data shows that the list price was greater than 130% of the payment using established methodology (a weighted median), CMS will recoup the difference from the laboratory through a payment claw back.
- Payment will be updated annually based on the weighted median of commercial payer reimbursement.

The expansion of government s role in the U.S. health care industry as a result of the ACA, and changes to the reimbursement amounts paid by Medicare and other payers for diagnostic tests may have a materially adverse effect on OncoCyte s business, financial condition, results of operations and cash flows.

Because of certain Medicare billing policies, OncoCyte may not receive complete reimbursement for tests provided to Medicare patients.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test or assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a diagnostic laboratory, may receive reimbursement from Medicare for the service. Regional policies are directed by Medicare s regional Medicare Administrative Contractors, or MACs. Reimbursement for diagnostic testing may be negatively impacted by California MAC policies.

TABLE OF CONTENTS

Long payment cycles of Medicare, Medicaid and other third-party payors, or other payment delays, could hurt OncoCyte s cash flows and increase its need for working capital.

Medicare and Medicaid have complex billing and documentation requirements that OncoCyte will have to satisfy in order to receive payment. Failure to comply with these requirements and other laws applicable to billing may result in, among other things, non-payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on OncoCyte s revenues and earnings. Similarly, the failure of private health insurers or other private third-party payers to properly process OncoCyte s payment claims in a timely manner could delay its receipt of payment for its diagnostic tests and services, which may have a material adverse effect on its cash flows.

Private health insurance company policies may deny coverage or limit the amount they will reimburse OncoCyte for the performance of its diagnostic tests.

Patients who are not covered by Medicare will generally rely on health insurance provided by private health insurance companies. If OncoCyte is considered a non-contracted provider by a third-party payer, that payer may not reimburse patients for diagnostic tests performed by OncoCyte or doctors within the payer s network of covered physicians may not use its services to perform diagnostic tests for their patients. As a result, OncoCyte may need to enter into contracts with health insurance companies or other private payers to provide diagnostic tests to their insured patients at specified rates of reimbursement which may be lower than the rates OncoCyte might otherwise collect.

Risks Pertaining to Our Common Stock

Our trading price may be volatile which could adversely affect the liquidity of our common stock.

The trading price of our common stock, like that of the shares of many biotechnology companies, has been highly volatile. The price of our shares of common stock may rise rapidly in response to certain events, such as the commencement of clinical trials of an experimental new therapy or diagnostic test, even though the outcome of those trials and the likelihood of ultimate FDA approval of a therapeutic product remain uncertain.

Similarly, price of our shares of common stock may fall rapidly in response to certain events such as unfavorable results of clinical trials or a delay or failure to obtain FDA approval. The failure of our earnings to meet analysts expectations could also result in a significant rapid decline in the market price of our shares of common stock.

These and other external factors have caused and may continue to cause the trading price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock, and may otherwise negatively affect the liquidity of our common stock.

Current economic and stock market conditions may adversely affect the price of our shares of common stock.

The stock market has been experiencing extreme price and volume fluctuations which have affected the market price of the equity securities without regard to the operating performance of the issuing companies. Broad market fluctuations, as well as general economic and political conditions, may adversely affect the market price of our shares of common stock.

Because we do not pay dividends, our shares of common stock may not be a suitable investment for anyone who needs to earn dividend income.

We do not pay cash dividends on our shares of common stock. For the foreseeable future, we anticipate that any earnings generated in our business will be used to finance the growth of our business and will not be paid out as dividends to holders of our shares of common stock. This means that our shares of common stock may not be a suitable investment for anyone who needs to earn income from their investments.

Securities analysts may not initiate coverage or continue to cover our shares of common stock and this may have a negative impact on the market price of our shares of common stock.

The trading market for our shares of common stock will depend, in part, on the research and reports that securities analysts publish about our business and our shares of common stock. We do not have any control over these analysts. If securities analysts do not cover our shares of common stock, the lack of research coverage may

TABLE OF CONTENTS

adversely affect the market price of those shares. If securities analysts do cover our shares of common stock, they could issue reports or recommendations that are unfavorable to the price of our shares of common stock, and they could downgrade a previously favorable report or recommendation, and in either case our share prices could decline as a result of the report. If one or more of these analysts does not initiate coverage, ceases to cover our shares of common stock or fails to publish regular reports on our business, we could lose visibility in the financial markets, which could cause our share prices or trading volume to decline.

Investors in our shares of common stock may experience dilution of their ownership interests because of the future issuance of additional shares of common stock and preferred shares by us.

In the future, we may issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present shareholders. We are currently authorized to issue an aggregate of 152,000,000 shares of capital stock consisting of 150,000,000 shares of common stock and 2,000,000 shares of preferred stock. There are no shares of preferred stock issued and outstanding. As of September 30, 2016, we had 103,392,248 issued shares of our common stock and 102,772,542 outstanding shares of our common stock. The difference of 619,706 issued shares of our common stock and outstanding shares of our common stock as of September 30, 2016 is attributed to shares held by our subsidiaries which are accounted for as treasury stock on our condensed consolidated balance sheet. As of September 30, 2016, 6,597,000 shares of common stock were reserved for issuance upon the exercise of outstanding options and vesting of restricted stock units under our employee stock option plans; and 9,394,862 shares reserved for issuance upon the exercise of warrants to purchase common stock, including the publicly traded warrants.

In addition, the operation of some of our subsidiaries has been financed in part through the sale of capital stock in those subsidiaries to private investors. Sales of additional subsidiary shares could reduce our ownership interest in the subsidiaries, and correspondingly dilute our shareholder s ownership interests in our consolidated enterprise. Certain of our subsidiaries also have their own stock option plans and the exercise of subsidiary stock options or the sale of restricted stock under those plans would also reduce our ownership interest in those subsidiaries, with a resulting dilutive effect on the ownership interest of our shareholders in our consolidated enterprise.

We may issue additional shares of common stock or other securities that are convertible into or exercisable for shares of common stock in order to raise additional capital, or in connection with hiring or retaining employees or consultants, or in connection with future acquisitions of licenses to technology or rights to acquire products, or in connection with future business acquisitions, or for other business purposes. The future issuance of any such additional shares of common stock or other securities may create downward pressure on the trading price of our shares of common stock.

We may also issue preferred stock having rights, preferences, and privileges senior to the rights of our shares of common stock with respect to dividends, rights to share in distributions of our assets if we liquidate our company, or voting rights. Any preferred stock may also be convertible into shares of common stock on terms that would be dilutive to holders of shares of common stock. Our subsidiaries may also issue their own preferred shares with a similar dilutive impact on our ownership of the subsidiaries.

The market price of our shares of common stock could be impacted by prices at which we sell shares in our subsidiaries and affiliates.

The operation of some our subsidiaries and affiliates has been financed in part through the sale of capital stock in those subsidiaries or affiliates, and our subsidiaries and affiliates may sell shares of their capital stock in the future for financing purposes. The prices at which our subsidiaries and affiliates may sell shares of their capital stock could impact the value of our company as a whole and could impact the price at which our shares of common stock trade in

the market. A sale of capital stock of one of our subsidiaries and affiliates at a price that the market perceives as low could adversely impact the market price of our shares of common stock. Even if our subsidiaries and affiliates sell their capital stock at prices that reflect arm s length negotiation with investors, those prices may not reflect a true fair market value or the ascribed value of the subsidiaries or affiliates based on those share prices may not be fully reflected in the market value of our shares of common stock.

TABLE OF CONTENTS

We have certain anti-takeover provisions in place.

Certain provisions of our Amended and Restated Articles of Incorporation and the California General Corporation Law could discourage a third-party from acquiring, or make it more difficult for a third-party to acquire, control of our company without approval of our Board of Directors. These provisions could also limit the price that certain investors might be willing to pay in the future for shares of our common stock. Certain provisions allow the Board of Directors to authorize the issuance of preferred stock with rights superior to those of the common stock. We are also subject to Section 1101(e) of the California General Corporation Law, which, among other things, limits the ability of a majority shareholder holding more than 50% but less than 90% of the outstanding shares of a California corporation from consummating a cash-out merger.

TABLE OF CONTENTS

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus supplement, the accompanying prospectus and in the documents incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements reflect our current views with respect to future events or our financial performance, and involve certain known and unknown risks, uncertainties and other factors, including those identified below, which may cause our or our industry s actual or future results, levels of activity, performance or achievements to differ materially from those expressed or implied by any forward-looking statements or from historical results. We intend the forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements include information concerning our possible or assumed future results of operations and statements preceded by, followed by, or that include the words may, will, could, would, should, believe, exp anticipate, intend, estimate, predict, potential or similar expressions.

Forward-looking statements are inherently subject to risks and uncertainties, many of which we cannot predict with accuracy and some of which we might not even anticipate. Although we believe that the expectations reflected in the forward-looking statements are based upon reasonable assumptions at the time made, we can give no assurance that the expectations will be achieved. Future events and actual results, financial and otherwise, may differ materially from the results discussed in the forward-looking statements. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus supplement. Readers are cautioned not to place undue reliance on these forward-looking statements. We have no duty to update or revise any forward-looking statements after the date of this prospectus supplement or to conform them to actual results, new information, future events or otherwise.

TABLE OF CONTENTS

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the shares of common stock we are offering will be approximately $, after deducting underwriting fees and estimated offering expenses payable by us, or approximately $ million if the underwriters exercise their over allotment option in full. We intend to use the net proceeds for general corporate purposes, including, without limitation, to fund clinical trials of products we are developing, to finance our research and develop programs, and for general working capital. As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses for the net proceeds that we will have from the sale of the shares of common stock. Accordingly, our management will have broad discretion in the application of the net proceeds. We may also use proceeds of this offering to acquire one or more businesses or new business assets. 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. Pending the application of the net proceeds, we expect to invest the proceeds in investment grade, interest bearing securities or money market funds.

TABLE OF CONTENTS

DIVIDEND POLICY

We have never paid cash dividends on our common stock and we do not anticipate paying cash dividends in the foreseeable future, but intend to retain our capital resources for reinvestment in our business. Any future determination to pay cash dividends on our common stock will be at the discretion of our Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements and other factors as the Board of Directors deems relevant.

TABLE OF CONTENTS

DILUTION

If you purchase shares of our common stock in this offering, your interest will be diluted to the extent of the difference between the public offering price per share and the net tangible book value per share of our common stock after this offering. We calculate net tangible book value per share by dividing our net tangible assets (tangible assets less total liabilities) by the number of shares of our common stock issued and outstanding as of September 30, 2016.

Our historical net tangible book value at September 30, 2016 was $125.39 million or approximately $1.22 per share. After giving effect to the sale of shares of common stock in this offering at an offering price of $ per share, and after deducting estimated offering expenses, our adjusted net tangible book value as of September 30, 2016 would have been approximately $ million, or approximately $ per share. This represents an immediate increase in the net tangible book value of $ per share of our common stock to our existing shareholders and an immediate dilution in net tangible book value of approximately $ per share to new investors. The following table illustrates per share dilution:

Public offering price per share		$
Net tangible book value per share as of September 30, 2016	$ 1.22	
Increase in net tangible book value per share attributable to this offering	$	
Adjusted net tangible book value per share as of September 30, 2016, after giving effect to this offering		$
Dilution per share to new investors purchasing shares in this offering		$

If the underwriters exercise in full their option to purchase additional shares of our common stock at a public offering price of $ per share, after deducting estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2016 would have been approximately $ million or approximately $ per share of common stock. This represents an immediate increase in net tangible book value per share of approximately $ per share to existing shareholders, and an immediate dilution of approximately $ per share to investors participating in this offering.

The above discussion and table is based on 102,772,542 shares of our common stock issued and outstanding as of September 30, 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 6,497,105 shares of common stock, with a weighted average exercise price of $3.61 per share;
- 100,000 restricted stock units issued to certain executives under our 2012 Equity Incentive Plan; and
- 3,516,000 shares of common stock available for issuance under our 2002 Stock Option Plan and our 2012 Equity Incentive Plan.

To the extent that outstanding options or warrants are exercised, or other shares are issued, investors purchasing shares in this offering could experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of those securities could result in further dilution to our shareholders.

S-29

TABLE OF CONTENTS

UNDERWRITING

We have entered into an underwriting agreement with the underwriters named below. Raymond James & Associates, Inc., or Raymond James, is acting as the sole book-running manager and representative of the underwriters. The underwriting agreement provides for the purchase of a specific number of shares of common stock by each of the underwriters. The underwriters obligations are several, which means that each underwriter is required to purchase a specified number of shares of common stock, but is not responsible for the commitment of any other underwriter to purchase shares of common stock. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase the number of shares of common stock set forth opposite its name below:

Underwriter	Number of Shares
Raymond James & Associates, Inc.	
Total	

The underwriters have agreed to purchase all of the shares of common stock offered by this prospectus supplement (other than those covered by the over allotment option described below) if any are purchased.

The shares of common stock offered hereby should be ready for delivery on or about February , 2017 against payment in immediately available funds.

The underwriters are offering the shares of common stock subject to various conditions and may reject all or part of any order. The representative of the underwriters has advised us that the underwriters propose to offer the common stock directly to the public at the public offering price that appears on the cover page of this prospectus supplement. After the shares of common stock are released for sale to the public, the representative may change the offering price and other selling terms at various times.

We have granted the underwriters an over allotment option. This option, which is exercisable for up to 30 days after the date of this prospectus supplement, permits the underwriters to purchase up to shares of common stock at a price of $ per share from us to cover over allotments, if any. If this option is exercised in full, the total gross proceeds will be $ million, and the total net proceeds to us will be $ million.

The following table provides information regarding the amount of the discounts and commissions to be paid to the underwriters by us, before expenses:

	Per Share	Total Without Exercise of Over allotment Option	Total With Full Exercise of Over allotment Option
Public offering price	$	$	$
Underwriting discounts and commissions	$	$	$
Proceeds, before expenses to us	$	$	$

One of our significant shareholders has indicated an interest in purchasing up to an aggregate of $ million in shares of our common stock in this offering at the offering price to the public. 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 shareholder, or the shareholder 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 shareholder as they will

on any other shares sold to the public in this offering.

We estimate that our total expenses of the offering, excluding the underwriting discounts and commissions, will be approximately $, which includes up to $125,000 that we have agreed to reimburse the underwriters for the fees and expenses incurred by them in connection with the offering.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

We, our officers, directors and certain of our stockholders have agreed to a 90-day lock-up with respect to shares of our common stock and other of our securities that they beneficially own, including securities that are

TABLE OF CONTENTS

convertible into shares of common stock and securities that are exchangeable or exercisable for shares of common stock. This means that, subject to certain exceptions, for a period of 90 days following the date of this prospectus supplement, we and such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of Raymond James.

Rules of the SEC may limit the ability of the underwriters to bid for or purchase shares before the distribution of the shares is completed. However, the underwriters may engage in the following activities in accordance with the rules:

Stabilizing transactions—The representative may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.

Over-allotments and syndicate covering transactions—The underwriters may sell more shares of our common stock in connection with this offering than the number of shares that they have committed to purchase. This over-allotment creates a short position for the underwriters. This short sales position may involve either covered short sales or naked short sales. Covered short sales are short sales made in an amount not greater than the underwriters over-allotment option to purchase additional shares in this offering described above. The underwriters may close out any covered short position either by exercising its over-allotment option or by purchasing shares in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market, as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the shares that could adversely affect investors who purchase shares in this offering.

Penalty bids—If the representative purchases shares in the open market in a stabilizing transaction or syndicate covering transaction, it may reclaim a selling concession from the underwriters and selling group members who sold those shares as part of this offering.

Passive market making—Market makers in the shares who are underwriters or prospective underwriters may make bids for or purchases of shares, subject to limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, the underwriters purchases to cover the syndicate short sales or to stabilize the market price of our common stock may have the effect of raising or maintaining the market price of our common stock or preventing or mitigating a decline in the market price of our common stock. As a result, the price of the shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages resales of the shares.

Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may occur on The NYSE MKT or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

Electronic Delivery of Prospectus Supplement: A prospectus supplement in electronic format may be delivered to potential investors by one or more of the underwriters participating in this offering. The prospectus supplement in electronic format will be identical to the paper version of such preliminary prospectus supplement. Other than the prospectus supplement in electronic format, the information on any underwriter s website and any information contained in any other website maintained by an underwriter is not part of this prospectus supplement, the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus form a part.

NOTICE TO NON-U.S. INVESTORS

Investors are advised to contact their legal, financial or tax advisers to obtain an independent assessment of the financial and tax consequences of an investment in shares.