

BIOTIME INC
Form 10-K
March 15, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 1-12830

BioTime, Inc.
(Exact name of registrant as specified in its charter)

California 94-3127919
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

1010 Atlantic Avenue, Suite 102
Alameda, California 94501
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (510) 521-3390

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Name of exchange on which registered
Common shares, no par value	NYSE MKT
Common share purchase warrants expiring October 1, 2018	NYSE MKT

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):
Yes No

The approximate aggregate market value of voting common shares held by non-affiliates computed by reference to the price at which common shares were last sold as of June 30, 2015 was \$165,569,534. Shares held by each executive officer and director and by each person who beneficially owns more than 5% of the outstanding common shares have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of common shares outstanding as of March 4, 2016 was 94,894,140.

Documents Incorporated by Reference

Portions of the registrant's Proxy Statement for 2016 Annual Meeting of Shareholders are incorporated by reference in Part III

BioTime, Inc.
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PART I

Statements made in this Form 10-K that are not historical facts may constitute forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those discussed. Words such as “expects,” “may,” “will,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” and similar expressions identify forward-looking statements. See “Risk Factors.”

References to “we” and “our” means BioTime, Inc. and its subsidiaries unless the context otherwise indicates.

The description or discussion, in this Form 10-K, of any contract or agreement is a summary only and is qualified in all respects by reference to the full text of the applicable contract or agreement.

INDUSTRY AND MARKET DATA

This Annual Report on Form 10-K contains market data and industry forecasts that were obtained from industry publications, third party market research and publicly available information. These publications generally state that the information contained therein has been obtained from sources believed to be reliable. While we believe that the information from these publications is reliable, we have not independently verified such information.

This Annual Report on Form 10-K also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this Report from our own research as well as from industry and general publications, surveys and studies conducted by third parties, some of which may not be publicly available. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

Item 1. Business

Overview

BioTime, Inc. is a clinical-stage biotechnology company focused on developing and commercializing novel therapies developed from two of our core technology platforms. We believe we have the world’s premier collection of pluripotent stem cell assets and the best cell delivery platform. The foundation of our core therapeutic technology platform is pluripotent stem cells that are capable of becoming any of the cell types in the human body. 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 pluripotent stem cell technology is complemented by our HyStem® 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.

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

identify and accelerate the development of potential breakthroughs in the treatment of various major diseases.

We and our subsidiaries now have four therapeutic product candidates in human clinical trials (See “Products and Product Candidates” elsewhere in this Report).

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Renevia®, a potential treatment for HIV related facial lipoatrophy, is currently in a pivotal clinical trial in Europe to assess its efficacy in restoring normal skin contours in patients whose subcutaneous fat, or adipose tissue, has been lost due to antiviral drug treatment for HIV. Renevia® consists of our cell-transplantation delivery matrix (HyStem®) combined with the patient's own adipose cells. Over time, we may discover that Renevia® has much broader applications beyond its use in patients with HIV.

AST-VAC1, a cancer immunotherapy with promising Phase II clinical trial data in acute myeloid leukemia ("AML"). Asterias currently plans to submit a request for a Special Protocol Assessment (SPA) to the FDA to confirm the primary endpoint and other design elements of this pivotal Phase 3 trial;

OpRegen®, a potential therapy derived from pluripotent stem cells for the treatment of the dry form of age-related macular degeneration ("AMD") is currently in a Phase I/IIa clinical trial; and

AST-OPC1, a potential therapy derived from pluripotent stem cells, is currently in a Phase I/II clinical trial for spinal cord injuries.

In addition, our collaborator Cancer Research UK is preparing to initiate a Phase I/II clinical trial of AST-VAC2 in non-small cell lung cancer, or NSCLC, 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.

In addition to the development of therapeutics that address large market opportunities, BioTime's research and other activities have resulted, over time, in the creation of subsidiaries that address other, non-therapeutic market opportunities.

OncoCyte Corporation (NYSE MKT: OCX) is developing cancer diagnostics and expects to introduce a liquid biopsy lung cancer confirmatory diagnostic test in 2017;

LifeMap Sciences, Inc. is marketing an integrated online database and other software research tools for biomedical and stem cell research;

LifeMap Solutions, Inc. is developing mobile health (mHealth) products; and

Ascendance Biotechnology, Inc. 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.

Strategy

We are transitioning BioTime into a clinical and commercial-ready company. Our near-term focus is to achieve three primary objectives:

- 1) Advancing key product development programs through clinical trials;
- 2) Simplifying the company structure to focus resources on the development of promising cell therapies that address large market opportunities; and
- 3) Unlocking value for BioTime shareholders from investments in subsidiaries.

To foster these goals, during 2015, we implemented a Co-CEO leadership team. Adi Mohanty, previously our Chief Operating Officer, was appointed Co-Chief Executive Officer and leads human clinical development, product commercialization, corporate and administrative functions. Dr. Michael D. West, our Co-Chief Executive Officer, who is one of the world's foremost experts on therapies derived from stem cells, leads science, product discovery, and preclinical product development programs.

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Key Accomplishments in 2015

We achieved numerous strategic accomplishments during 2015. We advanced several key development programs as we initiated patient recruitment and dosing in multiple clinical trials. We reported positive clinical and preclinical data at four annual scientific meetings that showed the promise of our product candidates AST-VAC1 and OpRegen®. We entered into collaborations designed to advance development programs. We continued unlocking the value of our subsidiaries with the distribution of OncoCyte Corporation ("OncoCyte") common stock to BioTime shareholders. OncoCyte common stock is now traded on the NYSE MKT under the symbol "OCX".

Clinical Progress

The first patients were successfully treated in BioTime's ongoing pivotal clinical trial in Europe assessing the efficacy of Renevia® for the treatment of HIV-associated lipoatrophy. We have opened additional clinical sites and expect to have the clinical trial fully enrolled in 2016.

Our subsidiary Asterias Biotherapeutics, Inc. ("Asterias") announced positive long-term follow-up data from a Phase II clinical trial of AST-VAC1 in patients with acute myeloid leukemia (AML) that showed more than 50% of those who received AST-VAC1 had prolonged relapse-free survival. Asterias discussed the clinical data during an oral presentation at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting.

Our subsidiary, Cell Cure Neurosciences, Ltd. ("Cell Cure Neurosciences"), began enrolling patients at Hadassah University Medical Center in Jerusalem, Israel, in a Phase I/IIa dose-escalation clinical trial evaluating the safety and efficacy of pluripotent stem cell-derived OpRegen® for geographic atrophy, the severe stage of the dry form of AMD. Cell Cure Neurosciences received Fast Track designation from the FDA for OpRegen® for the treatment of dry-AMD.

Asterias initiated patient enrollment and dosing in the SCiStar Phase I/IIa clinical trial of AST-OPC1 (oligodendrocyte progenitor cells) in patients with complete cervical spinal cord injury. Subsequently, Asterias concluded recruitment of the initial safety cohort, in which three patients were administered a low dose of 2 million AST-OPC1 cells. Following review of the 30-day post-injection safety data from the initial cohort, the Data Monitoring Committee, an independent group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing, recommended dose escalation of AST-OPC1 to the second cohort, and patient recruitment for the second cohort has commenced.

In a prospective clinical validation study, proprietary tests developed by our subsidiary OncoCyte for the non-invasive diagnosis of bladder cancer demonstrated a high level of sensitivity and specificity in the detection of urothelial carcinoma, the most common type of bladder cancer. This data was presented at the American Association for Cancer Research 2015 Annual Meeting.

At the American Thoracic Society International Conference, OncoCyte's collaborators at the Wistar Institute of Anatomy and Biology presented positive clinical interim results demonstrating the high level of observed sensitivity and specificity in the assayed samples of OncoCyte's blood-based diagnostic test designed to aid physicians in the early detection of lung cancer.

Patent Portfolio

- In 2015, BioTime and its subsidiaries collectively had 48 new patents issued worldwide.

Non-dilutive Funding

- Cell Cure Neurosciences was awarded a grant for 2015 of 6.24 million shekels (approximately \$1.61 million) from Israel's Office of the Chief Scientist (OCS) to help finance the development of OpRege[®].

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Collaborations

Asterias entered to a collaboration agreement with United Kingdom-based Cell Therapy Catapult to advance the development of large-scale manufacturing processes for AST-VAC2 as an allogeneic dendritic cell immunotherapy.

BioTime and Hepregen Corporation formed Ascendance Biotechnology, Inc. (“Ascendance”) by combining Hepregen’s cellular micro-patterning drug and chemical screening technologies with BioTime’s ESI-BIO research products and proprietary stem cell technologies.

Our subsidiary OrthoCyte Corporation (“OrthoCyte”) and Heraeus Medical GmbH entered into exclusive development and worldwide licensing agreements for the development of innovative bone grafting therapies to address unmet orthopedic needs based on the use of BioTime’s proprietary PureStem® human embryonic progenitor cell (“hEPC”) technology.

Other Company News

BioTime’s Board of Directors appointed Adi Mohanty to serve with Michael D. West as Co-Chief Executive Officer.

BioTime completed the distribution of approximately 4.75 million shares of common stock of its subsidiary OncoCyte to BioTime shareholders, resulting in OncoCyte becoming a publically traded company (NYSE MKT: OCX).

Additional Information

We are incorporated in the State of California. Our common shares trade on the NYSE MKT and the Tel Aviv Stock Exchange (“TASE”) under the symbol “BTX.” Our principal executive offices are located at 1010 Atlantic Avenue, Suite 102, Alameda, CA 94501, and our phone number at that address is (510) 521-3390. Our website address is www.biotimeinc.com. The information on, or that can be accessed through our website is not part of this Report. We also make available, free of charge through our website, our most recent annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after the reports are electronically filed with or furnished to the Securities and Exchange Commission (the “SEC”).

HyStem®, Hextend®, PureStem® and Renevia® are registered trademarks of BioTime, Inc., and ReGlyde™ and Premvia™ are trademarks of BioTime, Inc. ReCyte™ is a trademark of ReCyte Therapeutics, Inc. OpReg® is a registered trademark of Cell Cure Neurosciences, Ltd. HepatoPac® and HepatoMune® are registered trademarks of Ascendance Biotechnology, Inc. GeneCards® is a registered trademark of Yeda Research and Development Co. Ltd. LifeMap Discovery® is a registered trademark of LifeMap Sciences, Inc.

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Cell-based Products & Product Candidates

Our cell-based products and product candidates are based on one of two technologies: HyStem® cell delivery technology and pluripotent stem cells.

HyStem® Based Products & Product Candidates

Renevia®

We are developing Renevia®, a clinical grade HyStem® hydrogel, as an injectable product. 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. However, the transplantation of cells without the molecular matrix in which cells normally reside often leads to widespread cell death or the failure of the transplanted cells to remain at the transplant site. The transfer of cells in Renevia® may resolve this issue by localizing the transplanted cells at the intended site and by providing a three-dimensional scaffold upon which cells can rebuild normal tissue. Renevia® may also support other emerging cell and tissue transplant therapies such as those derived from pluripotent stem cells, in addition to its potential application in the treatment of a number of conditions such as osteoarthritis, brain cancer, stroke, bone fracture, and wounds.

We are conducting a multi-site pivotal clinical study in Spain to assess the efficacy of Renevia® as a delivery matrix for adipose cells to restore normal skin contours in patients where the subcutaneous adipose tissue has been lost to HIV related facial lipoatrophy. Lipoatrophy is a localized loss of fat beneath the skin and is often a consequence of the normal aging process, but lipoatrophy can also be associated with trauma, surgery, and diseases. Lipoatrophy is frequently experienced by HIV patients who have been treated with certain anti-viral drugs like Stavudine and Zidovudine. The resulting facial wasting ages the individual's appearance prematurely and, along with a thinning of the skin, allows musculature and vasculature to be easily seen, resulting in what is commonly known as "the face of AIDS". Treatment of the condition improves the individual's self-esteem and quality of life.

The pivotal clinical study design includes a minimum of 56 and up to 92 HIV positive males and females between 18-65 years of age. Subjects will be randomized with half in a treatment group and half in a delayed-treatment cohort, each receiving a single treatment procedure of Renevia® with autologous adipose cells harvested by liposuction and implanted in the mid-facial region. The primary effectiveness measure will be the comparison of the change in skin thickness between the treatment and delayed treatment groups. A secondary endpoint will be mid-face volume deficit and global aesthetic improvement scores. Patients are being monitored at one, three, and six-month intervals after treatment.

Renevia® is manufactured in the US in compliance with cGMP requirements and has been tested pursuant to ISO 10993 standards for implantable medical devices and shown to be biocompatible without adverse effects in animal studies. Our plan is to bring Renevia® to the medical market first in the European Union ("EU"). Once the use of Renevia® in surgery is established in the EU, we plan to seek approval from the FDA to market Renevia® in the US market where we may pursue approval for broader indications where appropriate regeneration of adipose tissue could be effective in other applications such as surgical reconstructive procedures.

Premvia™

Premvia™, is a HyStem® hydrogel formulation of cross-linked thiol-modified hyaluronan and thiol-modified gelatin for the management of wounds including partial and full-thickness wounds, ulcers, tunneled/undermined wounds, surgical wounds, and burns. Premvia™ utilizes the same cGMP components used in Renevia®. Although we received 510(k)

clearance from the FDA in August 2014 to market Premvia™ as a medical device for wound management, we are doing commercial assessment of the broader wound management area that includes breast cancer lumpectomy surgery before launching this product.

HyStem® Cell Delivery Technology

Renevia® and Premvia™ are based on our HyStem® cell delivery technology. Our HyStem® hydrogel product line is one of the components in our near-term revenue strategy. HyStem® is a patented biomaterial that mimics the extracellular matrix (“ECM”), the network of molecules surrounding cells in organs and tissues that is essential to cellular function. Many tissue engineering and regenerative cell-based therapies will require the delivery of therapeutic cells in a matrix or scaffold for proper function. HyStem® is a unique hydrogel that has been shown to support cellular attachment and proliferation in vivo. Current research at leading medical institutions has shown that HyStem® is compatible with a wide variety of tissue types including brain, bone, skin, neural, cartilage, and heart tissues.

The patented technology underlying our HyStem® hydrogels such as Renevia® and Premvia™ was developed at the University of Utah and has been licensed to us for human therapeutic uses. The HyStem® technology is based on a unique thiol cross-linking strategy to prepare hyaluronan-based hydrogels. Since the first published report in 2002, there have been over 150 academic scientific publications supporting the biocompatibility of thiol cross-linked hyaluronan based hydrogels and their applications as medical devices and in cell culture, tissue engineering, and animal models of cell-based therapies.

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The building blocks for HyStem® hydrogels are hyaluronan and in some applications, gelatin, each of which has been thiol-modified by carbodiimide mediated hydrazide chemistry. HyStem® hydrogels are formed by cross-linking mixtures of these thiolated macromolecules with polyethylene glycol diacrylate (“PEGDA”). This unique cross-linking chemistry works through an elegant chemical reaction between the acrylate groups on the PEGDA and the sulfhydryl groups on the thiolated macromolecules that does not generate any toxic by-products, pH change or heat. The rate of the cross-linking reaction turning the liquid mixture into a hydrogel (gelation rate) as well as hydrogel stiffness can be controlled by varying the amount of the PEGDA cross-linker. Due to the unique cross-linking chemistry, HyStem® hydrogels can be injected or applied as a liquid which allows the hydrogel to conform to the cavity or space, and gelation occurs in situ without harming the recipient tissue. This property of HyStem® hydrogels offers several distinct advantages over other hydrogels, including the possibility of mixing bioactive materials with the hydrogel at the point of use and the ability to inject or otherwise apply the material in its liquid state with precision at surgical or wound sites. Building upon this platform, we have developed the HyStem® family of unique, biocompatible resorbable hydrogels.

Cell Therapy Products and Product Candidates

OpRegen®

Cell Cure Neurosciences is developing cell therapies for retinal and neural degenerative diseases. Cell Cure Neurosciences’ principal product candidate is OpRegen®, a proprietary formulation of embryonic stem cell-derived retinal pigmented epithelial (“RPE”) cells developed to address the high, unmet medical needs of people suffering from dry AMD. OpRegen® consists of animal product-free RPE cells with high purity and potency that were derived from human embryonic progenitor cells using a proprietary directed differentiated method. OpRegen® is formulated as a suspension of RPE cells.

Preclinical studies in mice have shown that following a single subretinal injection of OpRegen® as a suspension of cells, the cells can rapidly organize into their natural monolayer structure and survive throughout the lifetime of the mice. OpRegen® is intended to be an “off-the-shelf” allogeneic product provided to retinal surgeons in an “easy to use” form for transplantation. Unlike other investigational treatments for dry-AMD and treatments for wet-AMD that require multiple, frequent injections into the eye, it is expected that OpRegen® would be administered in a single procedure, or once every several years.

On February 16, 2015, the clinical trial entitled “Phase I/IIa Dose Escalation Safety and Efficacy Study of Human Embryonic Stem Cell-Derived Retinal Pigment Epithelium Cells Transplanted Subretinally in Patients with Advanced Dry-Form Age-Related Macular Degeneration with Geographic Atrophy” was initiated in Hadassah University Medical Center in Jerusalem. As with any clinical trial whose primary objective is to evaluate the safety of the product, the eligibility criteria was defined to exclude patients with medical conditions that could compromise patient’s safety. This presents a particular challenge with elderly patients, where the screening assessments often reveal underlying medical conditions that were unknown. The high rate of screening failures (86%) has slowed patient recruitment.

To expand availability of recruitment to a larger patient population, we extended the study to an additional three sites in Israel that will allow us access to a significantly larger patient population. Two of these are members of the largest health maintenance organization in the country and one is the municipal hospital serving the largest metropolitan area in the country. All of these hospitals have access to much larger numbers of patients with retinal degenerative diseases. These new sites in Israel have been qualified and are currently under review by the Ethics Committee. We are in discussions to have US trial sites in 2016.

The study will evaluate three different dose regimens of OpRegen®. A total of 15 patients will be enrolled of which we anticipate that three patients will have been injected by May 2016. The patients will be 50 years of age or older,

with the advanced form of dry-AMD called geographic atrophy with absence of additional concomitant ocular disorders. The eye in which the disease has progressed the most will be treated, while the other eye will serve as a control. Following injection, the patients will be followed for 12 months at specified intervals, to evaluate the safety and tolerability of OpRegen®. Following the initial 12 month period, patients will continue to be evaluated at longer intervals for an additional period of time up to five years following injection. A secondary objective of the clinical trial is to evaluate the preliminary efficacy of OpRegen® treatment by assessing the changes in ophthalmological parameters as measured by various ophthalmological methods of primary medical relevance to quantify structural changes and rate of geographic atrophy progression.

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AMD is one of the major diseases of aging and is the leading eye disease responsible for visual impairment of elderly persons in the US, Europe and Australia. AMD affects the macula, which is the part of the retina responsible for sharp, central vision that is important for facial recognition, reading and driving. There are two forms of AMD, the dry form and the wet form. The dry form or dry-AMD advances slowly and painlessly but may progress to geographic atrophy in which RPE cells and photoreceptors degenerate and are lost. Once the atrophy involves the fovea (the center of the macula), patients lose their central vision and may develop legal blindness. The U.S. Centers for Disease Control and Prevention estimate that about 1.8 million people in the U.S. have advanced-stage AMD, while another 7.3 million have an earlier stage of AMD and are at risk of vision impairment from the disease. Most people are afflicted with the dry form of the disease, for which there is currently no effective treatment. One of the most promising future therapies for age-related AMD is the replacement of the layer of damaged RPE cells that support and nourish the retina.

Cell Cure Neurosciences' research and development is conducted at Hadassah University Hospital, through research and consulting agreements with Hadasit Bio-Holding's ("HBL") affiliate Hadasit Medical Research Services and Development, Ltd. ("Hadasit"), under the direction of Professor Benjamin E. Reubinoff, Cell Cure Neurosciences' Chief Scientific Officer and Professor Eyal Banin, Cell Cure Neurosciences' Clinical Affairs Consultant.

Our Ownership of Cell Cure Neurosciences

We presently own, directly and through our subsidiary ES Cell International Pte Ltd. ("ESI"), approximately 62.5% of the outstanding ordinary shares of Cell Cure Neurosciences. We also hold certain Cell Cure Neurosciences convertible promissory notes that entitle us to acquire additional Cell Cure Neurosciences ordinary shares by converting those notes into ordinary shares. If we were to convert the convertible promissory notes into Cell Cure Neurosciences ordinary shares, and if no other ordinary shares are issued to third parties, our percentage ownership of Cell Cure Neurosciences would increase to 70%, based on the number of ordinary shares outstanding on February 28, 2016. Cell Cure Neurosciences has adopted a stock option plan under which it may issue up to 14,100 of its ordinary shares to officers, directors, employees, and consultants. As of December 31, 2015, options to purchase 12,240 ordinary shares of common stock had been granted.

We and ESI have entered into a Third Amended and Restated Shareholders Agreement with Cell Cure Neurosciences and its other principal shareholders Teva Pharmaceutical Industries, Ltd. ("Teva") and HBL pertaining to certain corporate governance matters and rights of first refusal among the shareholders to purchase on a pro rata basis any additional shares that Cell Cure Neurosciences may issue. Under the agreement, the shareholders also granted each other a right of first refusal to purchase any Cell Cure Neurosciences shares that they may determine to sell or otherwise transfer in the future. The number of members on the Cell Cure Neurosciences board of directors will be set at seven, of which we will be entitled to elect four directors, HBL will be entitled to elect two directors, and Teva will be entitled to elect one director. These provisions were also included in an amendment to Cell Cure Neurosciences' Articles of Association.

AST-VAC1: Autologous Telomerase-loaded, Dendritic Cells

AST-VAC1 is an autologous (patient-specific) cancer vaccine designed to stimulate a patient's immune system to attack telomerase. Asterias is developing AST-VAC1 for the treatment of Acute Myeloid Leukemia ("AML"), the most common form of acute leukemia in adults. There is a significant unmet clinical need, especially in high risk patients ineligible for stem cell transplant, who face poor outcomes and have limited therapies available to them. AST-VAC1 has the potential to supplement current chemotherapy regimens in order to improve long-term remission for these patients.

AST-VAC1 is prepared from patient-specific white blood cells, or monocytes, using a sequential process that differentiates the monocytes into dendritic cells. Dendritic cells play an important role in teaching the immune system

what to attack. The patient-specific dendritic cells are then loaded with telomerase and a sequence called LAMP, which enhances immunostimulatory activity. AST-VAC1 is stored frozen, which enables Asterias to inventory several years of treatment drug from a single manufacturing process. After the initial production, the product is easily available for subsequent administrations. AST-VAC1 is injected into the patient's skin, with the objective of having the dendritic cells to travel to the lymph nodes and instruct cytotoxic T-cells to kill tumor cells expressing telomerase.

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A Phase II clinical trial of AST-VAC1 was conducted at six U.S. medical centers in intermediate and high-risk AML patients who had achieved complete clinical remission using standard chemotherapy regimens. The primary objectives and endpoints of this study were the feasibility of manufacturing AST-VAC1, along with the safety and tolerability of the vaccine in patients with AML in complete remission at screening. This trial completed patient enrollment in December 2009. Patients with AML entered the study in their first or second complete remission. Prior to, or shortly after, completing consolidation chemotherapy, patients underwent leukapheresis, a process of collecting white blood cells directly from the patient. AST-VAC1 was produced at a centralized manufacturing facility from the patient-specific white blood cells. Patient blood cells were differentiated to dendritic cells in culture, modified to express telomerase linked to the LAMP targeting signal, divided into single doses and frozen. AST-VAC1 was released for patient dosing contingent on several specifications that included identity of mature dendritic cells, confirmation of telomerase expression, number of viable cells per dose after thawing, and product sterility.

AST-VAC1 was successfully manufactured and released in 24 out of the 33 patients enrolled in the study. Three patients relapsed prior to vaccination, therefore only 21 of the 24 patients for whom AST-VAC1 was successfully manufactured and released received vaccine. The 21 patients were vaccinated weekly for six weeks, with AST-VAC1 administered just below the surface of the skin, followed by a non-treatment period of four weeks, and then subsequent booster injections every other week for 12 weeks. Monthly extended booster injections were then administered until the vaccine product supply was depleted or the patient relapsed.

Twenty-one patients received AST-VAC1 in the study, including 19 in clinical remission and two in early relapse. AST-VAC1 was found to have a favorable safety and tolerability profile in this study over multiple vaccinations, with up to 32 serial vaccinations administered (median = 17). One serious adverse event deemed possibly related to AST-VAC1, grade 3-4 idiopathic thrombocytopenic purpura, or bleeding into the skin caused by low platelets in blood, was reported. Four patients experienced serious adverse events deemed unrelated to AST-VAC1, including cyopenias associated with impending relapse (2), hypertension (1), and appendicitis with perforation/obstruction, hypokalemia (1). Fourteen patients experienced other grade 1 and 2 toxicities, primarily rash, fatigue, or headache. These data from the Phase I/II trial were presented at the December 2010 American Society of Hematology annual meeting.

Patient immune response to telomerase after vaccination with AST-VAC1 was evaluated using a test called the enzyme-linked immunosorbent spot ("ELISPOT") assay to measure the presence of activated T-cells specific to hTERT. Positive immune responses were detected in 55% of patients.

Asterias has performed follow-up data collection on the 19 patients who were treated while in complete remission to determine the long term effects of the AST-VAC1 administration on remission duration and disease-free survival. The results of this data collection were reported in an oral presentation at the American Society of Clinical Oncology annual meeting in May 2015. Eleven of 19 patients (58%) remained in complete remission at a median follow-up of 52 months. These results compare to historical data suggesting that between 20-40% of patients would be expected to be relapse free at 3-4 years. Additionally, of the 7 patients in the higher risk over 60 year old group, 4 (57%) remained relapse free at a median follow up of 54 months. Historically, relapse free survival rates in this population have been 10-20% at 3-4 years.

Asterias has conducted an End of Phase II meeting with the FDA with the goal of reviewing the proposed clinical development plan for AST-VAC1. In February 2016, Asterias announced that the FDA indicated general agreement with Asterias' proposed development plan for registration of AST-VAC1 through a single Phase III trial to support an accelerated development pathway and Biologics License Application ("BLA") filing. In this study, Asterias will assess the impact of AST-VAC1 compared to placebo on the duration of relapse-free-survival as the primary endpoint, and on overall survival as the secondary endpoint in patients who have achieved complete remission using standard therapies. The proposed trial will include AML patients 60 years and older, along with younger individuals who are at high risk for relapse and are not candidates for allogeneic bone marrow transplantation. Pending positive results, this

trial could be the basis for accelerated approval of AST-VAC1. Asterias currently plans to submit a request for a Special Protocol Assessment to the FDA to confirm the primary endpoint and other design elements of this pivotal Phase III trial.

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AST-OPC1 Oligodendrocyte Progenitor Cells for Spinal Cord Injury and Other Neurodegenerative Diseases

AST-OPC1 is being developed by Asterias. AST- OPC1 is comprised of oligodendrocyte progenitor cells, which are cells that become oligodendrocytes after injection, derived from a cGMP master cell bank of undifferentiated human embryonic stem (hES) cells that has been fully qualified for human use. These cells, which are stored frozen until ready for use, are produced under cGMP conditions and released for clinical use based on pre-determined specifications.

Oligodendrocytes are nature's nerve insulating cells. Like the insulation covering an electrical wire, oligodendrocytes enable the conduction of electrical impulses along nerve fibers, or axons, throughout the central and peripheral nervous system. They also promote neural growth, as well as induce blood vessel formation around nerve axons. AST-OPC1 cells reproduce all of the natural functions of oligodendrocytes in animal models, including: producing myelin that wraps around nerve fibers; producing neurotrophic factors which encourage regrowth or repair of nerve tissues, neuro-regeneration and sprouting of new nerve endings, and inducing new blood vessels which provide nutrients and remove waste matter from neural tissue as it functions in the body.

The spinal cord is a bundle of nerves that runs down the middle of the back and carries signals back and forth between the body and the brain. A spinal cord injury, or SCI, involves extensive loss of the myelin sheath produced by oligodendrocytes at the site of injury resulting in a disruption of those signals.

There are currently no drugs approved by the FDA specifically for the treatment of spinal cord injury, although methylprednisolone, a corticosteroid generally used as an anti-inflammatory drug, is sometimes prescribed on an off-label basis to reduce acute inflammation in the injured spinal cord immediately after injury. In order to effect substantial benefit in treating this complex injury, multiple mechanisms of action are required, such as re-myelination of the damaged axons, generation of new blood vessels to repair the ischemic damage from injury caused by lack of blood flow, and the presence of proteins that cause neuro-sprouting or new nerve growth to enable the severed axons to repair.

Multiple preclinical studies in a rat model of spinal cord injury have been performed using AST-OPC1. These studies have shown that a single injection of AST-OPC1 cells at the site of injury produces durable re-myelination, new blood vessel formation, and new neuronal sprouting, all of which result in sustained and significant improvement in the animal's locomotion within several months after injection.

Phase I Safety Trial

AST-OPC1 was tested in patients with acute SCI in a Phase I trial that was initiated in October 2010. The trial was an open label design conducted at seven U.S. neuro-trauma sites. Five subjects were treated in the trial between October 2010 and November 2011, each of whom had a sub-acute functional complete thoracic SCI. Patients enrolled in the study received a single dose of two million cells at the injury site between seven and 14 days after injury. All subjects received temporary low dose immune suppression treatment for 60 days. Delivery of AST-OPC1 was successful in all five subjects with no serious adverse events associated with the administration of the cells, with AST-OPC1 itself, or the immunosuppressive regimen. In four of the five subjects, serial MRI scans indicated that reduced spinal cord cavitation, or empty space, may have occurred. Immune monitoring, conducted in some of the patients, has not detected any evidence of immune responses to AST-OPC1 at time periods of up to one year post-transplant. This trial met the primary endpoints of safety and feasibility when administered to five patients with neurologically complete, thoracic SCI. The patients then entered a separate protocol after the first year which is following them annually in person in years 2-5 and via annual phone calls through 15 years.

As of March 14, 2016, the first patient has completed all five years of their in person follow-up data set and the remaining four patients have completed their four year follow-up data set. Under the long term follow-up protocol

there have continued to be no significant adverse events to date in any patient attributable to the AST-OPC1 product, the surgery to deliver the cells, or the immunosuppressive regimen. There have been no unexpected neurological changes to date, nor has there been evidence of adverse changes or cavitation on multiple MRIs. MRI results in four of the five subjects continue to be consistent with prevention of lesion cavity formation.

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Phase I/IIa Dose Escalation Study: Subjects with Neurologically Complete Cervical Spinal Cord Injuries

Based on the results of the completed Phase I trial of AST-OPC1 in thoracic SCI, Asterias obtained permission from the FDA in August 2014 to initiate a Phase I/IIa dose escalation trial in patients with neurologically complete cervical SCI. Individuals with neurologically complete cervical SCI have a loss of function in all four limbs, as well as multiple additional impairments such as impaired bowel and bladder function, reduced sensation, spasticity, sudden changes in blood pressure, deep vein thrombosis, sexual dysfunction, increased infections, skin pressure sores, and chronic pain. Medical treatment options are limited and these individuals frequently require significant assistance for their care and activities of daily living.

Scientifically, the injured cervical spinal cord is a much better location than the upper or middle back spinal cord to test the safety and potential activity of AST-OPC1. This is partly due to the fact that damaged and demyelinated nerve axons in these areas of the back need to regrow over several spinal segments in order to restore nerve function. In contrast, damaged and demyelinated nerve axons in cervical injuries only need to regrow a short distance to restore such function.

Asterias initiated enrollment of the Phase I/IIa dose escalation trial of AST-OPC1 in patients with complete cervical SCI in March 2015. The clinical trial, the “SCIStar study” is designed to assess safety and activity of three escalating doses of AST-OPC1 in complete cervical SCI, the first targeted indication for AST-OPC1. The SCI-Star trial is an open-label, single-arm study in patients with sub-acute, C-5 to C-7, neurologically complete cervical SCI. These individuals have lost all sensation and movement below their injury site with severe paralysis of the upper and lower limbs. Clinical investigators will evaluate the safety of AST-OPC1 administered once between 14 and 30 days after injury and also assess the impact on patient hand and arm function.

Asterias completed enrollment in the first 2 million cell dose cohort in August 2015. No serious adverse events related to AST-OPC1, the administration procedure, or the immunosuppressive regimen have been observed to date. The study is currently open for enrollment in the second 10 million cell cohort. Following collection of initial safety data from this second dose cohort, Asterias plans to seek FDA concurrence to increase the robustness of the proof of concept in the Phase I/IIa clinical trial by expanding enrollment.

The FDA has granted Orphan Drug Designation of AST-OPC1 for the treatment of acute SCI.

AST-OPC1 CIRM Grant

The California Institute for Regenerative Medicine, or CIRM, provided Asterias with a Strategic Partnerships Award grant that provides for up to \$14.3 million of non-dilutive funding for the Phase I/IIa clinical trial and other product development activities for AST-OPC1, subject to achieving certain milestones. The grant will provide partial funding for the SCIStar trial and for product development efforts to refine and scale manufacturing methods to support commercialization. CIRM will disburse the grant funds subject to Asterias contingent on the achievement of certain specific progress milestones. As the distributions of the CIRM grant are subject to meeting certain milestones, there can be no assurance that Asterias will receive the entire amount granted. In addition, pursuant to the Award, Asterias agreed to notify and report to CIRM information relating to serious adverse events, studies, press releases clinical trial information and routine communications in accordance with an agreed schedule.

As of December 31, 2015 Asterias had received \$6.6 million in funding from CIRM. Failure to timely achieve milestones or otherwise satisfy CIRM regarding any delay could lead CIRM to suspend payments. The foregoing description of the arrangement with CIRM is a summary only and is qualified by reference to the Notice of Grant Award, dated as of October 16, 2014, and the Amendment to Notice of Grant Award, dated as of March 2016.

Asterias will need to raise additional capital in order conduct the Phase I/IIa clinical trial and any subsequent clinical trial and product development work. Asterias intends to apply for a supplementary CIRM grant to provide funding for the clinical trial expansion.

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AST-VAC2: hES Cell-Derived Allogeneic Dendritic Cells

AST-VAC2 is being developed by Asterias as an allogeneic, or non-patient specific, cancer vaccine candidate designed to stimulate patient immune responses to telomerase. AST-VAC2 is produced from hES cells that can be modified with any antigen. The use of hES, as opposed to collecting and using the patient's own blood, as the starting material for AST-VAC2 provides a scalable system for the production of a large number of vaccine doses in a single lot. Allogeneic vaccine production has the potential to have lower manufacturing costs, "off-the-shelf" availability and broader patient availability, and ensure product consistency. In addition, this approach has the potential to stimulate a more robust immune response through an adjuvant effect of the immune mismatch between the genetic makeup of AST-VAC2 and patients. Further, AST-VAC2 may be synergistic with immune checkpoint inhibitors currently in development for many cancer indications. This is because immune checkpoint inhibitors function by relieving suppressive mechanisms exerted on T-cells by the tumor, whereas AST-VAC2 is designed to specifically target the T-cells to attack the telomerase expressing tumor cells.

Product Development Strategy for AST-VAC2

During September 2014, Asterias entered into a Clinical Trial and Option Agreement (the "CRUK Agreement") with Cancer Research UK ("CRUK") and Cancer Research Technology Limited, ("CRT"), a wholly-owned subsidiary of CRUK, pursuant to which CRUK has agreed to fund Phase I/II clinical development of AST-VAC2 loaded with the same LAMP-telomerase construct used in AST-VAC1. Under the terms of the CRUK Agreement, Asterias is responsible, at their own cost, for completing process development and manufacturing scale-up of the AST-VAC2 manufacturing process and transferring the resulting cGMP-compatible process to CRUK. CRUK is responsible, at its own cost, for manufacturing clinical grade AST-VAC2 and for carrying out the Phase I/IIa clinical trial of AST-VAC2.

Asterias has completed the technology transfer of the AST-VAC2 manufacturing process to CRUK and CRUK is now verifying and scaling up the production of AST-VAC2 in its facility in preparation for pilot and full cGMP campaigns. Upon successful completion of these activities, CRUK's Centre for Drug Development ("CDD") will submit a Clinical Trial Authorisation application to the UK regulatory authorities for the Phase I/II clinical trial in non-small cell lung cancer, which will be sponsored, managed and funded by CDD. The clinical trial will examine the safety, immunogenicity and activity of AST-VAC2 and position the immunotherapy to be tested for numerous clinical indications. Asterias will continue to serve in a collaborative and advisory role with CRUK throughout this process.

Upon completion of the Phase I/II trial, Asterias will have an exclusive first option to acquire the data generated in the trial. If Asterias exercises that option Asterias will be obligated to make payments upon the execution of the license agreement, upon the achievement of various milestones, and then royalties on sales of products. In connection with the CRUK Agreement, Asterias sublicensed to CRUK for use in the clinical trials and product manufacturing process certain patents that have been licensed or sublicensed to Asterias by third parties. Asterias would also be obligated to make payments to those licensors and sublicensors upon the achievement of various milestones, and then royalties on sales of products if AST-VAC2 is successfully developed and commercialized.

Our Ownership of Asterias

As of March 8, 2016, we owned 56.7% of the outstanding Asterias common stock. Asterias common stock is listed for trading on the NYSE MKT under the symbol AST. Asterias has adopted an Equity Incentive Plan under which Asterias has reserved 8,000,000 shares of common stock for the grant of stock options, and other equity-based awards to officers, directors, employees, and consultants. As of December 31, 2015, Asterias had outstanding options to purchase a total of 5,130,105 shares of Asterias common stock and 48,304 restricted stock units.

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OrthoCyte: Osteochondral Progenitor Cells for Bone Grafting and Other Orthopedic Indications

Research and Development and License Agreements with Heraeus Medical GmbH

OrthoCyte is our wholly owned subsidiary developing cellular therapeutics for orthopedic disorders. During September 2015, OrthoCyte entered into a License Agreement and a Research and Development Agreement with Heraeus Medical GmbH (“Heraeus”), for the development of innovative bone grafting therapies based on the use of our proprietary PureStem® human embryonic progenitor cell (hEPC) technology. Pursuant to the terms of the Research and Development Agreement, OrthoCyte will carry out a research and development project aimed at producing a cell therapy bone grafting product, using PureStem® technology and either HyStem® scaffold technology for delivery of bioactives, or scaffold technology owned by Heraeus or licensed to Heraeus from third parties.

While OrthoCyte is presently concentrating its efforts on developing bone grafting products the Heraeus sponsored program, OrthoCyte may also, if sufficient funding becomes available, test the utility of various osteochondral PureStem® cells that display potential to differentiate into cartilage-like tissues such as intervertebral disc tissue. Cartilage defects and disease affect our aging population. In particular osteoarthritis and spinal disc degeneration have a significant impact on the mobility and health of an aging population. Chronic back pain is one of the largest unmet health economic burdens in modern society. With more than 85% lifetime prevalence, nearly everyone is affected in their lifetime. In most cases, chronic back pain stems from the progressive degeneration of the avascular intervertebral disc tissue that cushions the vertebrae in the spinal column. This tissue is structurally and functionally similar to other cartilage tissues. Currently there are no treatment options for people suffering from degenerative disc disease other than risky invasive surgery to fuse the affected discs. A therapy that would slow down or reverse disc degeneration to delay or avoid surgery would have a great impact in the largest musculoskeletal unmet need. Various biologic approaches using growth factors or cells from different adult tissues are in various phases of preclinical and early clinical development, but so far none have proven to work effectively. The opportunity for OrthoCyte to screen, and select a candidate with the appropriate attributes to effectively impact the disease process is an important differentiating factor from other competing technologies.

Our Ownership of OrthoCyte

As of March 8, 2016, we owned 100% of the outstanding common stock of OrthoCyte. OrthoCyte has adopted a stock option plan under which it may issue up to 4,000,000 shares of its common stock to officers, directors, employees, and consultants of OrthoCyte and BioTime. As of December 31, 2015, options to purchase 2,629,166 shares of OrthoCyte common stock had been granted.

ReCyte Therapeutics—Treatment of Vascular Disorders

Our subsidiary ReCyte Therapeutics, Inc. (“ReCyte Therapeutics”) focuses on developing treatments for vascular disorders, including both age-related diseases and injuries. The therapeutic indications targeted by ReCyte Therapeutics products include age-related cardiovascular diseases such as coronary artery disease, heart failure, and peripheral artery disease. Therapeutics for age-related vascular disease represent some of the largest, fastest-growing actual and potential markets in the U.S. due to the aging baby boom generation. Cardiovascular disease is among the leading causes of death and disability in the U.S., and they consume a major and every-increasing proportion of health care costs. The National Academy of Sciences has estimated that a potential 58 million Americans are currently afflicted with cardiovascular disease. ReCyte Therapeutics is working to produce novel first-in-class therapies for the unmet needs of these patients. Its products in development include vascular cells derived from pluripotent stem cell sources.

During August 2011, BioTime entered into a License Agreement with Cornell University for the worldwide development and commercialization of technology developed invented by Dr. Shahin Rafii and co-workers at Weill

Cornell Medical College for the differentiation of pluripotent stem cells into vascular endothelial cells. ReCyte Therapeutics has used the Cornell technology in combination with the PureStem® technology to produce highly purified monoclonal embryonic vascular endothelial progenitor stem cells.

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Our Ownership of ReCyte Therapeutics

As of March 8, 2016, we owned 94.8% of the ReCyte Therapeutics common stock outstanding. The other shares of ReCyte Therapeutics common stock outstanding are owned by two private investors. ReCyte Therapeutics has adopted a stock option plan under which it may issue up to 4,000,000 shares of its common stock to officers, directors, employees, and consultants of ReCyte Therapeutics and BioTime. As of December 31, 2015, options to purchase 1,279,166 shares of ReCyte Therapeutics common stock had been granted.

OncoCyte: Novel Cancer Diagnostics

OncoCyte is developing highly accurate, easy to administer, non-invasive liquid biopsy diagnostic tests in areas of high unmet need in oncology. OncoCyte's primary focus is confirmatory diagnostics that are used in conjunction with imaging to confirm initial diagnoses. In addition, OncoCyte will be developing screening diagnostics as potential replacements for screening imaging procedures that do not meet the needs of patients, health care providers or payers. For some indications, OncoCyte will also be pursuing the probability of recurrence of a specific cancer through the development of prognostics; or companion diagnostics that help a physician determine which therapy is the optimal treatment for the patient.

Liquid Biopsy Tests for Diagnosis of Cancer

OncoCyte's current development strategy for cancer diagnostic tests is to evaluate and validate specific diagnostics using methods of detecting proteins, messenger RNA ("mRNA") or a micro RNA ("miRNA") approach. Based on substantial unmet needs, large markets, and data generated thus far from patient serum or urine screening, OncoCyte is focusing its efforts on biomarkers associated with lung, breast and bladder cancers, and especially on detectable amounts of several cancer-associated biomarkers in patients with early-stage disease. The analysis of blood or urine samples to detect or confirm the presence of cancer is known as a "liquid biopsy."

The relative ease of administering a liquid biopsy diagnostic and cost savings due to the elimination of more costly and invasive biopsy procedures, OncoCyte believes will make liquid biopsy diagnostic tests useful as routine tests that could be performed in men and women of any age and at any desired frequency to detect lung, breast and bladder cancer. If successfully developed, these tests will initially reduce diagnosis uncertainty and eliminate unnecessary down-stream procedures resulting from indeterminate Low Dose Computed Tomography ("LDCT") screening, cytology or mammogram tests.

Once development of a liquid biopsy diagnostic test is completed, OncoCyte may commence marketing that diagnostic test for one or more specific kinds of use which relate to the kind of diagnostic evaluation that a physician is performing for a patient. The diagnostics may take one or more of four different types of use depending on the type of cancer and the performance of the diagnostic. These intended uses include:

Confirmatory diagnostics – confirmatory diagnostics are used in conjunction with a current standard of care screening procedure. For example, a lung confirmatory diagnostic would be used in conjunction with LDCT to confirm a suspicious result by yielding a secondary suspicious versus benign result. In the case of the benign results, patients would not need additional invasive procedures to determine the presence of cancer. In the case of the suspicious results, additional procedures would be highly warranted;

Screening diagnostics – screening diagnostics would replace or be used as an alternative to existing screening procedures. A screener diagnostic for breast cancer could be used as an alternative to MRIs for women with a family history of breast cancer, BRCA mutations or dense breast tissue. This test could become part of a routine annual or other periodic physical examination;

Recurrence diagnostics also known as prognostics – are used for patients who had previously been diagnosed with cancer but are currently in remission. In the case of a bladder diagnostic, the test could be used in lieu of a painful, costly cystoscopy to confirm whether the cancer has returned. This test could become part of the follow-up of bladder cancer patients; and

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Companion diagnostics – used by physicians to help determine an optimal therapy for a specific patient. An example of this would be HER2+ and Herceptin.

OncoCyt plans to start the process to establish a laboratory in mid-2016, including ordering the equipment and hiring the personnel, for which it will apply for registration and certification under the Clinical Laboratory Improvements Amendment (“CLIA”). OncoCyt intends to initially develop and market a lung cancer diagnostic test in the United States before seeking regulatory approvals required to market the diagnostic test in other countries. The test developed will be a blood screening test for cancer markers, which will be regulated under CLIA as a laboratory diagnostic test (“LDT”). OncoCyt may also pursue approvals from the FDA or through the European Directive on in vitro diagnostics (“IVDs”) for any in vitro IVDs that it may develop.

The Development Pathway

OncoCyt’s liquid biopsy diagnostic tests for cancer will each go through four stages of development prior to commercialization: the research stage; assay development; validation studies; and CLIA validation. Clinical utility studies will also be conducted after commencement of the marketing of a diagnostic test.

The first stage of the development of a CLIA LDT is the research stage. In the research stage of a molecular diagnostic, biological markers are analyzed to determine if specific markers are differentially expressed in certain diseases. OncoCyt is developing blood and urine tests that differentiate malignant patient samples from benign patient samples by looking at differences in the amount of specific mRNA and miRNA expressed in whole blood or urine. The objective of this phase of the development process is to delineate promising biomarkers.

In the second stage, assay development, the best performing biomarkers are combined into an assay. The optimal combination of biomarkers that are to be utilized in the final diagnostic are determined through bioinformatics and machine learning software strategies, and assay/marker reliability and usability. The end result of this stage is a “locked down” assay.

The locked down assay is first engineered and tested for reliability, reproducibility, accuracy, precision and stability in series of research and development studies, which we refer to as R&D validation studies, that result in the validation of the assay. In these R&D validation studies, blinded samples are run through the assay to confirm that the results reported by the assay are consistent across an appropriate range of real world, day to day variables including operating temperature variances and sample differences.

After the completion of the R&D validation study, studies and analysis are run in the CLIA laboratory – the laboratory where the diagnostic will be performed after commercial launch – in order to confirm the reliability of the diagnostic test and the full test system in the clinical environment. The CLIA validation phase confirms that the diagnostic test being used routinely in the clinical oncology market meets the appropriate regulatory and clinical standards. Successful completion of this stage results in the finalization and lockdown of the commercial diagnostic test system. At this point, the laboratory undergoes the inspection and certification process, which allows the marketing of the diagnostic in specific states or countries.

The final phase of the diagnostic pathway occurs after the final diagnostic test has been launched and consists of carrying out one or more clinical utility studies. These studies are important for obtaining coverage and reimbursement by payers such as Medicare, Medicaid, third party commercial insurers, health maintenance organizations, and large corporations that self-insure. Clinical utility studies analyze the healthcare economics associated with a diagnostic test, and in particular whether it results in overall patient benefits and decreased expenditures for the healthcare system. These studies track the progress of patients who have had the diagnostic test administered; for those patients where the diagnostic test has ruled out the possibility of a disease, downstream procedures are tracked to see if physician behavior has changed. The results of this phase may be published in peer

review journals and are generally compiled in dossiers to share with managed care groups, including both public and commercial payers. Obtaining positive results in clinical utility studies is very important in obtaining positive coverage and reimbursement decisions by payers.

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For example, in OncoCyte's first product candidate - the lung confirmatory diagnostic - patients who have received a suspicious finding in LDCT screening will be tested with the diagnostic. During post marketing clinical utility studies, OncoCyte will track patients with a benign result to see if any unnecessary downstream procedures such as bronchoscopy or surgical biopsy are still performed in order to determine whether OncoCyte's diagnostic test prevents unnecessary procedures and reduces the overall cost of diagnosing lung cancer, or whether the test is used in addition to downstream procedures, and thereby increases overall costs.

OncoCyte's three most advanced diagnostic tests (lung, breast and bladder cancer tests) are in the assay development stage. OncoCyte anticipates that its lung cancer diagnostic test will move into the R&D validation stage in 2016 and finish the CLIA validation stage by early 2017, but there can be no assurance that the development of that diagnostic test will advance in that time frame.

Clinical Trials—Lung Cancer Diagnostic

OncoCyte is collaborating with The Wistar Institute of Anatomy and Biology ("Wistar") to develop the confirmatory lung cancer diagnostic test through a large, multi-site clinical study. This collaboration involves the development of a prototype assay and a clinical study with over 2,000 blood samples obtained at six clinical sites from patients with a high-risk profile for development of lung cancer.

Large clinical trials are needed to produce patient subsamples that ensure the development of a highly reliable, accurate diagnostic test. In the case of the lung cancer trials, samples are being collected from patients who are at risk for lung cancer, based on having positive or suspicious results from LDCT screening, and who have undergone biopsies to determine the pathology results. Additionally, OncoCyte will collect samples from patients who used alternative screening procedures such as chest x-rays and who were referred for biopsies.

OncoCyte and Wistar investigators are currently assessing gene expression patterns in blood cells of patients with malignant lung disease and patients with non-malignant lung disease. Preliminary analysis of patient data from this study was completed during the first quarter of 2015 and preliminary findings from the research showed a sensitivity of 76% and a specificity of 88%. Sensitivity refers to the probability of detecting the presence of the disease accurately; while specificity refers to the probability of accurately predicting not having the disease.

Data concerning the OncoCyte/Wistar preliminary lung assay performance with initial biomarkers and classifiers was presented at the American Thoracic Society in May of 2015. The OncoCyte/Wistar preliminary lung assay had a false positive rate of only 12%. In comparison, National Lung Screening Test results reported in the New England Journal of Medicine (August 2011) showed that LDCTs have a very high false positive rate of approximately 96%.

Sensitivity is the probability of detecting the presence of the disease accurately. A sensitivity of 76% means that three out of four cancers were detected. Specificity is the probability of accurately predicting not having the disease. In this case, approximately 9 out of 10 people without the disease were predicted. A false positive rate is a function of specificity and is equal to 1 minus specificity or 12% in this case.

Clinical Trials—Bladder Cancer Diagnostic

OncoCyte initiated a clinical trial in January 2014 for its bladder cancer diagnostic test that has been expanded to a multi-site trial. The trial will involve up to 1,600 patient samples obtained from at least nine large urology clinics located throughout the United States. Patient enrollment as of March 2016 is approximately 79% complete with almost 1,260 samples in house. The clinical trial is designed to expand the potential use of a bladder cancer test beyond pathology laboratories and into urologic practices at the point of cystoscopy. The goal of the current clinical trial is to compare the performance of OncoCyte's bladder cancer markers to the performance of cystoscopy. Investigators in the trial are collecting urine samples from patients undergoing cystoscopy for the diagnosis of either

primary or recurrent bladder cancer. Cystoscopy and biopsy results will be compared with the results of OncoCyte's proprietary diagnostic test panel in determining the overall performance of the classifier and markers.

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In May of 2015, OncoCyte presented preliminary findings of its bladder research at the American Association of Cancer Research. Preliminary findings showed a sensitivity of 90% and a specificity of 83%. A sensitivity of 90% means that 9 out of 10 cancers were detected. Specificity is the probability of accurately predicting not having the disease. OncoCyte expects that the inclusion of additional markers will improve the diagnostics sensitivity and specificity further.

Clinical Trials-- Breast Cancer Diagnostic

OncoCyte has tested the performance of its cancer markers in detecting breast cancer in a set of 134 samples from patients with confirmed cases of breast cancer. The outcome of this initial experiment led to the start of prospective clinical trials during the first quarter of 2014 with the sponsorship of a 1,200 patient study at four clinical sites. As of March of 2016, OncoCyte has collected over 900 patient blood samples. Data from this and ongoing studies will be used to support an initial use of the breast cancer diagnostic test by radiologists to aid in determining the malignancy potential of suspicious mammography findings.

Our Ownership of OncoCyte

On December 31, 2015, we distributed to our shareholders on a pro rata basis a portion of the shares of OncoCyte common stock we then owned. As of March 8, 2016 we owned 57.8% of the OncoCyte common stock outstanding. OncoCyte common stock is listed for trading on the NYSE MKT under the symbol OCX. OncoCyte has adopted a stock option plan under which it may issue up to 4,000,000 shares of its common stock to officers, directors, employees, and consultants of OncoCyte and BioTime. As of December 31, 2015, options to purchase 2,239,583 shares of OncoCyte common stock had been granted.

LifeMap Sciences: Data Bases and Tools for Biomedical, Gene, Stem Cell, and Disease Research

LifeMap Sciences markets GeneCards® the leading human gene database, as part of an integrated database suite that includes LifeMap Discovery® the database of embryonic development, stem cell research and regenerative medicine; and MalaCards™, the human disease database and the analysis tools VarElect™, a powerful, yet easy-to-use application for prioritizing gene variants resulting from next generation sequencing experiments, and GeneAnalytics™, a novel gene set analysis tool. LifeMap Sciences makes its databases and analysis tools available for use by researchers at pharmaceutical and biotechnology companies and other institutions through paid subscriptions or on a fee per use basis. Academic institutions have free access to use the databases. The analysis tools are offered to academic users through paid subscriptions.

Our Ownership of LifeMap Sciences

As of March 8, 2016, we owned 77.9% of the LifeMap Sciences common stock outstanding. The other shares of LifeMap Sciences common stock outstanding are owned by certain officers and directors of LifeMap Sciences and by other investors. LifeMap Sciences has adopted a stock option plan under which it may issue up to 2,342,269 shares of its common stock to officers, directors, employees, and consultants of LifeMap Sciences and BioTime. As of December 31, 2015, options to purchase 1,795,096 shares of LifeMap Sciences common stock had been granted.

LifeMap Solutions: Mobile health software

Our subsidiary LifeMap Sciences formed a wholly owned subsidiary, LifeMap Solutions, to develop personal mobile health software products intended to connect users with their complex personal health information and other big data. LifeMap Solutions has entered into a Co-Development and Option Agreement with the Icahn School of Medicine at Mount Sinai, a nonprofit education corporation ("Mount Sinai"), pursuant to which LifeMap Solutions and Mount Sinai have agreed to work cooperatively to develop internet, web-based, mobile user or consumer software products to

provide users with information that may potentially aid them in improving lifestyle and healthcare decisions and outcomes. The planned products are envisioned to provide information based on interpretations of one or more components of: clinical, genetic, wearable device, and other data relating to human disease, health or wellness. LifeMap Solutions may develop products with different capabilities directed to different users, such as products for consumer use and products for use by physicians or other medical professionals. The determination to develop and include particular features or capabilities in different versions of the product, and the timing of the release of different product versions to intended markets, may be influenced by the position of the FDA as to whether those features or capabilities would cause a product to be regulated as a medical device.

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Ownership of LifeMap Solutions

LifeMap Sciences presently owns 100% of the outstanding common stock of LifeMap Solutions. LifeMap Solutions has adopted a stock option plan under which it may issue up to 18,667 shares of its common stock to officers, directors, employees, and consultants of LifeMap Solutions, LifeMap Sciences, and BioTime. As of December 31, 2015, options to purchase 14,034 shares of LifeMap Solutions common stock had been granted.

Ascendance Biotechnology: Research Products and Services for Drug Development and Screening and Basic Research

HepatoPac® and HepatoMune™ for Drug Development and Safety Testing and Ascendance Biotechnology

Ascendance was formed to provide complete, in vitro turn-key, product development solutions to the pharmaceutical, biotechnology, chemical, and cosmetics industries, all of which are in the business of creating new chemical entities (“NCEs”) and/or new biologics.

To create living models of human organs Ascendance, using foundational technology licensed from the Massachusetts Institute of Technology (“MIT”) created a proprietary process of “micropatterning” human and animal cells onto plates in a similar manner that “chips” are made in the electronics industry. These plates form the primary components of Ascendance’s application-directed assay kits, which are used for drug discovery, in vitro metabolite analysis and safety testing of NCEs, including new drug candidates.

Ascendance’s HepatoPac® and HepatoMune® assay kits replace or augment existing methods that rely on random mixed cell cultures or simple suspensions of cells in a growth medium for testing. The result is the generation of more accurate predictive and mechanistic data that can be used to distinguish toxic or metabolically unsuitable drug candidates or other NCEs from those most likely to be safe and effective.

Products for Research

Ascendance also produces and sells research products previously sold by BioTime through its ESI-BIO division, including the PureStem® cells and research grade HyStem® hydrogel products.

Equity Method Investment in Ascendance

As of March 8, 2016 we owned 46.1% of the outstanding common stock of Ascendance.

Pluripotent Stem Cell Lines for Clinical Research Use

Because pluripotent stem cells have the ability to transform into any cell type in the human body, they may provide a means of producing a host of new products of interest to medical researchers. It is likely that pluripotent stem cells could be used to develop new cell lines designed to rebuild cell and tissue function otherwise lost due to degenerative disease or injury.

In 2007, ESI announced the world’s first human embryonic stem (“hES”) stem cell lines derived under cGMP principles. The FDA enforces cGMP regulations with respect to the manufacturing of human therapeutics for use in the U.S., and virtually every country across the globe maintains some analogous standards for quality control in the manufacture of therapeutic products for humans.

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ESI and scientists from Sydney IVF, Australia's leading center for infertility and in vitro fertilization ("IVF") treatment, also published a scientific report, "The Generation of Six Clinical-Grade Human Embryonic Stem Cell Lines" (Cell Stem Cell 1: 490-494). The paper outlined the procedures used to document the production of clinical-grade pluripotent stem cell lines derived on human feeder cells obtained from an FDA approved source, produced in a licensed cGMP facility, with donor consent and medical screening of donors. Combined with our PureStem® technology that allows for the derivation of a wide array of hEPCs with high levels of purity and scalability, and site-specific homeobox gene expression, we believe that ESI's clinical-grade master cell banks may be used to generate clonal clinical-grade embryonic progenitor cells of great interest to the biopharmaceutical industry. We expect that the acquisition of ESI's clinical-grade pluripotent stem cell bank will save years of development time and thereby accelerate the development of clinical-grade progenitor cells for potential use as research and therapeutic products.

ESI's six cGMP pluripotent hES cell lines have been approved by the NIH for inclusion in the Human Embryonic Stem Cell Registry, which renders those cell lines eligible for use in federally funded research.

We have derived the complete genome sequence of five of the ESI pluripotent stem cell lines to facilitate the development of products derived from these cell lines. We have made these cGMP-grade cell lines, along with certain documentation and complete genomic DNA sequence information, available for sale. We will charge a price for the cGMP-grade cell lines that covers our production and delivery costs. Although no royalties will be payable to us by researchers who acquire the cell lines for research use, researchers who desire to use the cGMP cell lines for therapeutic or diagnostic products, or for any other commercial purposes, may do so only after signing commercialization agreements acceptable to us.

Plasma Volume Expanders and Related Products

Our business was initially focused on blood plasma volume expanders and related technology for use in surgery, emergency trauma treatment, and other applications. Our first product, Hextend®, is a physiologically balanced blood plasma volume expander used for the treatment of hypovolemia, a condition caused by low blood volume, often due to blood loss during surgery or injury. Hextend® maintains circulatory system fluid volume and blood pressure and helps sustain vital organs during surgery. Hextend®, approved for use in major surgery, is the only blood plasma volume expander that contains lactate, multiple electrolytes, glucose, and a medically approved form of starch called hetastarch. Hextend® is sterile and thus its use avoids the risk of infection. Health insurance reimbursements and HMO coverage now include the cost of Hextend® used in surgical procedures.

Hextend® has been formulated to maintain the patient's tissue and organ function by sustaining the patient's fluid volume and physiological balance. Hextend® is composed of a hydroxyethyl starch, electrolytes, sugar, and lactate in an aqueous base. Certain clinical test results indicate that Hextend® is effective at maintaining blood calcium levels when it is used to replace lost blood volume. Calcium can be a significant factor in regulating blood clotting and cardiac function. Clinical studies have also shown that Hextend® is better at maintaining the acid-base balance than are saline-based surgical fluids.

The Market for Plasma Volume Expanders

Blood transfusions are often necessary during surgical procedures and are sometimes required to treat patients suffering severe blood loss due to traumatic injury. Many surgical and trauma cases do not require blood transfusions but do involve significant bleeding that can place a patient at risk of suffering from shock caused by the loss of fluid volume (or hypovolemia) and physiological balance. Whole blood and packed red cells generally cannot be administered to a patient until the patient's blood has been typed and sufficient units of compatible blood or red cells can be located. Periodic shortages of supply of donated human blood are not uncommon, and rare blood types are often difficult to locate. The use of human blood products also poses the risk of exposing the patient to blood-borne diseases such as AIDS and hepatitis.

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Due to the risks and cost of using human blood products, even when a sufficient supply of compatible blood is available, physicians treating patients suffering blood loss are generally not permitted to transfuse red blood cells until the patient's level of red blood cells has fallen to a level known as the "transfusion trigger." During the course of surgery, while blood volume is being lost, the patient is infused with plasma volume expanders to maintain adequate blood circulation. During the surgical procedure, red blood cells are not generally replaced until the patient has lost approximately 45% to 50% of his or her red blood cells, thus reaching the transfusion trigger, at which point the transfusion of red blood cells may be required. After the transfusion of red blood cells, the patient may continue to experience blood volume loss, which will be treated with plasma volume expanders. Even in those patients who do not require a transfusion, physicians routinely administer plasma volume expanders to maintain sufficient fluid volume to permit the available red blood cells to circulate throughout the body and to maintain the patient's physiological balance.

Several units of fluid replacement products are often administered during surgery. The number of units will vary depending upon the amount of blood loss and the kind of plasma volume expander administered. Crystalloid products must be used in larger volumes than those required with colloid products such as Hextend®.

Licensing and Sale of Plasma Volume Expander Products

Hospira

Hospira, Inc. ("Hospira"), now a subsidiary of Pfizer, Inc., has the exclusive right to manufacture and sell Hextend® in the U.S. and Canada under a license agreement with us. Hospira is presently marketing Hextend® in the U.S. Hospira's license applies to all current therapeutic uses.

Hospira pays us a royalty on total annual net sales of Hextend®. The royalty rate is 5% plus an additional 0.22% for each \$1.0 million of annual net sales, up to a maximum royalty rate of 36%. The royalty rate for each year is applied on a total net sales basis. Hospira's obligation to pay royalties on sales of Hextend® will expire on a country-by-country basis when all patents protecting Hextend® in the applicable country expire and any third party obtains certain regulatory approvals to market a generic equivalent product in that country. The relevant composition patents began to expire in 2014 and the relevant methods of use patents expire in 2019.

We have the right to convert Hospira's exclusive license to a non-exclusive license or to terminate the license outright if certain minimum sales and royalty payments are not met. In order to terminate the license outright, we would pay a termination fee in an amount ranging from the milestone payments we received to an amount equal to three times the prior year's net sales, depending upon when termination occurs. Hospira has agreed to manufacture Hextend® for sale by us in the event that the exclusive license is terminated.

CJ Health

CJ HealthCare Corporation ("CJ Health"), a subsidiary of CheilJedang Corporation markets Hextend® in South Korea under an exclusive license from us. CJ Health paid us a license fee to acquire their right to market Hextend®. CJ Health also pays us a royalty on sales of Hextend®. The royalty will range from \$1.30 to \$2.60 per 500 ml unit of product sold, depending upon the price approved by Korea's National Health Insurance.

Subsidiaries

The joint ownership of subsidiaries with other investors has allowed us to fund a portion of the expensive development costs of certain products in a manner that spreads the costs and risk and reduces our need to obtain more equity financing of our own that could be dilutive to our shareholders. This structure also allows investors the flexibility to invest in BioTime, which is a broad portfolio of companies focused on regenerative medicine, or to

invest in a particular subsidiary that is targeting a specific field of medicine or a specific product market. We have provided funding, through cash infusions, loan facilities and the issuance of our stock, and we may continue to partly or wholly fund our subsidiaries, recruit their management teams, license to them or assist them in acquiring technology, and provide general guidance for building the subsidiary companies.

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The following table shows our operating subsidiaries, their respective principal fields of business, our percentage ownership, directly and through subsidiaries, as of December 31, 2015, and the country where their principal business is located:

Subsidiary	Field of Business	BioTime Ownership	Country
Ascendance Biotechnology, Inc.	HepatoPac® and HepatoMune® micro-patterned liver products and stem cell research products	46.1% ⁽¹⁾	USA
Asterias Biotherapeutics, Inc. (NYSE MKT: AST)	Therapeutic products derived from pluripotent stem cells, and immunotherapy products. Clinical programs include: AST-OPC1 for spinal cord injury, AST-VAC1 for acute myelogenous leukemia, and AST-VAC2 for non-small cell lung cancer	57.1%	USA
Cell Cure Neurosciences Ltd.	Products to treat age related macular degeneration (“AMD”) and neurological diseases. Lead product OpRegen® is in a Phase I/IIa clinical trial treating the dry form of AMD that afflicts 90% of patients with AMD	62.5% ⁽²⁾	Israel
ES Cell International Pte Ltd	Stem cell products for research, including clinical grade cell lines produced under current good manufacturing procedures (cGMP)	100%	Singapore
LifeMap Sciences, Inc.	Biomedical, gene, disease, and stem cell databases and research tools	77.9%	USA
LifeMap Sciences, Ltd.	Biomedical, gene, disease, and stem cell databases and research tools	(3)	Israel
LifeMap Solutions, Inc.	Mobile health software	(3)	USA
OncoCyte Corporation ⁽³⁾ (NYSE MKT: OCX)	Proprietary non-invasive, liquid biopsy and diagnostics for lung, breast and bladder cancers	57.7%	USA
OrthoCyte Corporation	Bone grafting products for orthopedic diseases and injuries	100%	USA
ReCyte Therapeutics, Inc.	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	94.8%	USA

(1)Includes shares owned by BioTime, ESI and ReCyte.

(2)Includes shares owned by BioTime and ESI.

(3)LifeMap Sciences, Ltd. and LifeMap Solutions, Inc. are wholly-owned subsidiaries of LifeMap Sciences, Inc.

Licensed Technology and Product Development Agreements

We have obtained the right to use technology that we believe has great potential in our product development efforts, and that may be useful to other companies that are engaged in the research and development of products for human therapeutic and diagnostic use.

Wisconsin Alumni Research Foundation—Research Products

We have entered into a Commercial License and Option Agreement with Wisconsin Alumni Research Foundation (“WARF”). The WARF license permits us and our subsidiaries to use certain patented and patent pending technology belonging to WARF, as well as certain stem cell materials, for research and development purposes, and for the production and marketing of “research products” and “related products.” “Research products” are products used as research tools, including in drug discovery and development. “Related products” are products other than research products, diagnostic products, or therapeutic products. “Diagnostic products” are products or services used in the diagnosis,

prognosis, screening or detection of disease in humans. “Therapeutic products” are products or services used in the treatment of disease in humans.

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We will pay WARF royalties on the sale of products and services under the WARF license. The royalty is 4% on the sale of research products and services and 2% on the sale of related products. The royalty is payable on sales by us or by any sublicensee. The royalty rate is subject to certain reductions if we also become obligated to pay royalties to a third party in order to sell a product.

We have an option to negotiate with WARF to obtain a license to manufacture and market therapeutic products, excluding products in certain fields of use. The issuance of a license for therapeutic products would depend upon our submission and WARF's acceptance of a product development plan, and our reaching agreement with WARF on the commercial terms of the license such as a license fee, royalties, patent reimbursement fees, and other contractual matters.

The WARF license shall remain in effect until the expiration of the latest expiration date of the licensed patents. However, we may terminate the WARF license prior to the expiration date by giving WARF at least 90 days written notice, and WARF may terminate the WARF license if we fail to make any payment to WARF, fail to submit any required report to WARF, or commit any breach of any other covenant in the WARF license, and we fail to remedy the breach or default within 90 days after written notice from WARF. The WARF license may also be terminated by WARF if we commit any act of bankruptcy, become insolvent, are unable to pay our debts as they become due, file a petition under any bankruptcy or insolvency act, or have any such petition filed against us which is not dismissed within 60 days, or if we offer our creditors any component of the patents or materials covered by the WARF license.

Wisconsin Alumni Research Foundation License to Asterias—Therapeutic Products, Diagnostic and Research Products

Asterias has entered into a Non-Exclusive License Agreement with WARF under which Asterias was granted a worldwide non-exclusive license under certain WARF patents and WARF-owned embryonic stem cell lines to develop and commercialize therapeutic, diagnostic and research products. The licensed patents include patents covering methods for growth and differentiation of primate embryonic stem cells. The licensed stem cell lines include the H1, H7, H9, H13 and H14 human embryonic stem cell lines.

In consideration of the rights licensed, Asterias has agreed to pay WARF an upfront license fee, payments upon the attainment of specified clinical development milestones, royalties on sales of commercialized products, and, subject to certain exclusions, a percentage of any payments that Asterias may receive from any sublicenses that it may grant to use the licensed patents or stem cell lines.

The license agreement will terminate with respect to licensed patents upon the expiration of the last licensed patent to expire. Asterias may terminate the license agreement at any time by giving WARF prior written notice. WARF may terminate the license agreement if payments of earned royalties, once begun, cease for a specified period of time or if Asterias and any third parties collaborating or cooperating with Asterias in the development of products using the licensed patents or stem cell lines fail to spend a specified minimum amount on research and development of products relating to the licensed patents or stem cell lines for a specified period of time.

WARF also has the right to terminate the license agreement if Asterias breaches the license agreement or becomes bankrupt or insolvent or if any of the licensed patents or stem cell lines are offered to creditors.

Asterias will indemnify WARF and certain other designated affiliated entities from liability arising out of or relating to the death or injury of any person or damage to property due to the sale, marketing, use, or manufacture of products that are covered by the licensed patents, or licensed stem cells, or inventions or materials developed or derived from the licensed patents or stem cell lines

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PureStem® Technology

ReCyte Therapeutics entered into a license agreement with Advanced Cell Technology, Inc., which later became Ocata Therapeutics, Inc. (“Ocata”) that was subsequently assigned to us under which we acquired exclusive world-wide rights to use Ocata’s technology for methods to accelerate the isolation of novel cell strains from pluripotent stem cells. The licensed rights include pending patent applications, know-how, and existing cells and cell lines developed using the technology.

The licensed technology is designed to provide a large-scale and reproducible method of isolating clonally purified human embryonic progenitor cells (“hEPCs”), many of which may be capable of extended propagation in vitro. Initial testing suggests that the technology may be used to isolate at least 200 distinct clones that contain many previously uncharacterized cell types derived from all germ layers that display diverse embryo- and site-specific homeobox gene expression. Despite the expression of many oncofetal genes, none of the hEPC tested led to tumor formation when transplanted into immunocompromised mice. The cells studied appear to have a finite replicative lifespan but have longer telomeres than most fetal- or adult-derived cells, which may facilitate their use in the manufacture of purified lineages for research and human therapy. Information concerning the technology was published in the May 2008 edition of the journal *Regenerative Medicine*.

BioTime has the right to use the licensed technology and cell lines for research purpose and for the development of therapeutic and diagnostic products for human and veterinary use, and also has the right to grant sublicenses. We paid Ocata a \$250,000 license fee as well as an 8% royalty on sales of products, services, and processes that utilize the licensed technology. Once a total of \$1.0 million of royalties has been paid, no further royalties will be due.

Ocata may reacquire royalty-free, worldwide licenses to use the technology for RPE cells, hemangioblasts, and myocardial cells, on an exclusive basis, and for hepatocytes, on a non-exclusive basis, for human therapeutic use. Ocata will pay us \$5,000 for each license that it elects to reacquire.

The term of the licenses from Ocata expire on the later of July 9, 2028 or the expiration of the last to expire of the licensed patents. The patent expiration dates cannot be presently determined with certainty because the patents are pending. Ocata may terminate the license agreement if we commit a breach or default in the performance of our obligations under the agreement and fail to cure the breach or default within the permitted cure periods. BioTime has the right to terminate the license agreement at any time by giving Ocata three months prior notice and paying all amounts due Ocata through the effective date of the termination.

HyStem® Hydrogel Technology

We have acquired a license from the University of Utah to use certain patents in the production and sale of hydrogel products, including our HyStem® products. We have a worldwide license for all uses of the licensed patents, with the exception of veterinary medicine and animal health. Our licensed field of use includes, but is not limited to, all human pharmaceutical and medical device applications, all tissue engineering and regenerative medicine uses, and all research applications.

Under the License Agreement, we will pay a 3% royalty on sales of products and services performed that utilize the licensed patents. We are obligated to pay minimum royalties to the extent that actual royalties on products sales and services utilizing the patents are less than the minimum royalty amount. The minimum royalty amounts are \$30,000 per annum during the term of the License Agreement. We will also pay the University of Utah 30% of any sublicense fees or royalties received under any sublicense of the licensed patents.

We will also pay a \$225,000 milestone fee within six months after the first sale of a “tissue engineered product” that utilizes a licensed patent. A tissue engineered product is defined as living human tissues or cells on a polymer

platform, created at a place other than the point-of-care facility, for transplantation into a human patient.

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We agreed to pay and an additional license fee for the additional rights licensed to us during August 2012, and the costs of filing, prosecuting, enforcing and maintaining the patents exclusively licensed to us, and a portion of those costs for patents that have been licensed to a third party for a different field of use.

Commencing in August 2017, we may, under certain circumstances, be obligated to sublicense to one or more third parties, on commercially reasonable terms to be negotiated between us and each prospective sublicensee, or re-grant to the University, rights to use the licensed patents for products and services outside the general industry in which we or any of our affiliates or sublicensees is then developing or commercializing, or has plans to develop or commercialize, a product using the licensed technology.

Research and Development Agreement and License Agreement with Heraeus

OrthoCyte has entered into a License Agreement and a Research and Development Agreement with Heraeus for the development of innovative bone grafting therapies based on the use of our proprietary PureStem® human embryonic progenitor cell technology. Pursuant to the terms of the Research and Development Agreement, OrthoCyte will carry out a research and development project aimed at producing a cell therapy bone grafting product, using PureStem® technology and either HyStem® scaffold technology for delivery of bioactives, referred to as the OrthoCyte Technology, or scaffold technology owned by Heraeus or licensed to it by third parties, referred to as the Heraeus Technology. The OrthoCyte Technology includes technology owned by it or BioTime or licensed from third parties.

Under the terms of the Research and Development Agreement, Heraeus agreed to make certain payments to OrthoCyte upon achieving certain milestones, of which \$1.0 million was paid during 2015, and will reimburse OrthoCyte for all costs and expenses incurred in connection with the project. Results of the project, including with respect to the product developed, that directly relate to the OrthoCyte Technology, or that incorporate into or embody the OrthoCyte Technology in the product, will be owned by OrthoCyte, both within and outside the field of use, subject to Heraeus' rights under the Research and Development Agreement and the License Agreement. Results of the project, including with respect to the product, that directly relate to the Heraeus Technology, or that incorporate or embody the Heraeus Technology in the product, will be owned by Heraeus, both within and outside the field of use, subject to OrthoCyte's rights under the License Agreement. The Research and Development Agreement provides that OrthoCyte will manufacture the product, but would assist Heraeus in establishing a second manufacturing source if requested, in each case pursuant to a manufacturing and supply agreement to be negotiated between the parties.

The Research and Development Agreement is effective until the completion and payment of the last milestone set forth in the project plan, but may be terminated by either party immediately upon written notice to the other party if the other party fails to remedy any material breach of the agreement within 90 days following receipt of written notice of such breach. In addition, Heraeus may terminate the Research and Development Agreement (i) if the product is not merchantable or fit for use in the field of use, (ii) if a milestone cannot be fulfilled in the view of OrthoCyte, (iii) in the case either OrthoCyte's or Heraeus' technology used in the product infringes a third party's intellectual property rights, or (iv) by written notice to OrthoCyte within 14 days following achievement of a milestone and payment to OrthoCyte of any milestone payments due.

Pursuant to the terms of the License Agreement, OrthoCyte has licensed the OrthoCyte Technology to Heraeus, and Heraeus has licensed the Heraeus Technology to OrthoCyte. The license grant by OrthoCyte to Heraeus is exclusive and worldwide in the field of bone grafting for all osteoskelton diseases and injuries, except oral maxilla-facial. The license grant by Heraeus to OrthoCyte is exclusive and worldwide in all other fields. Pursuant to the License Agreement, each of Heraeus and OrthoCyte will pay certain specified royalties to each other based on their respective net sales of the product developed in the research and development project. The License Agreement contains customary confidentiality obligations and representations and warranties. The License Agreement has a term expiring on the last to expire of the OrthoCyte patents licensed to Heraeus under the agreement, but may be terminated earlier (i) by Heraeus, at its sole discretion, on six months' prior written notice or (ii) by either party for cause, such as default

by the other party in any of its material obligations under the agreement which remains uncured for 60 days following written notice of the default, the other party challenges the intellectual property rights of the terminating party or the other party suffers an event of insolvency or bankruptcy. In addition, the License Agreement will terminate if the Research and Development Agreement is terminated prior to the launch of the product.

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Telomerase Sublicense

Asterias has received from Geron Corporation (“Geron”) an exclusive sublicense under certain patents owned by the University of Colorado’s University License Equity Holdings, Inc. relating to telomerase (the “Telomerase Sublicense”). The Telomerase Sublicense entitles Asterias to use the technology covered by the patents in the development of AST-VAC1 and AST-VAC2 as immunological treatments for cancer. Under the Telomerase Sublicense, Asterias paid Geron a one-time upfront license fee of \$65,000, and will pay Geron an annual license maintenance fee of \$10,000 due on each anniversary of the effective date of the Telomerase Sublicense, and a 1% royalty on sales of any products that Asterias may develop and commercialize that are covered by the sublicensed patents. The Telomerase Sublicense will expire concurrently with the expiration of Geron’s license. That license will terminate during April 2017 when the licensed patents expire. The Telomerase Sublicense may also be terminated by Asterias by giving Geron 90 days written notice, by Asterias or by Geron if the other party breaches its obligations under the sublicense agreement and fails to cure their breach within the prescribed time period, or by Asterias or by Geron upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other party.

Asterias is obligated to indemnify Geron, Geron’s licensor, and certain other parties for certain liabilities, including those for personal injury, product liability, or property damage relating to or arising from the manufacture, use, promotion or sale of a product, or the use by any person of a product made, created, sold or otherwise transferred by Asterias or its sublicensees that is covered by the patents sublicensed under the agreement.

License Agreement with the University of California

Geron assigned to Asterias its Exclusive License Agreement with The Regents of the University of California for patents covering a method for directing the differentiation of multipotential human embryonic stem cells to glial-restricted progenitor cells that generate pure populations of oligodendrocytes for remyelination and treatment of spinal cord injury. Pursuant to this agreement, Asterias has an exclusive worldwide license under such patents, including the right to grant sublicenses, to create products for biological research, drug screening, and human therapy using the licensed patents. Under the license agreement, Asterias will be obligated to pay the university a royalty of 1% from sales of products that are covered by the licensed patent rights, and a minimum annual royalty of \$5,000 starting in the year in which the first sale of a product covered by any licensed patent rights occurs, and continuing for the life of the applicable patent right under the agreement. The royalty payments due are subject to reduction, but not by more than 50%, to the extent of any payments that Asterias may be obligated to pay to a third party for the use of patents or other intellectual property licensed from the third party in order to make, have made, use, sell, or import products or otherwise exercise its rights under the Exclusive License Agreement. Asterias will be obligated to pay the university 7.5% of any proceeds, excluding debt financing and equity investments, and certain reimbursements, that it receives from sublicensees, other than Asterias’ affiliates and joint ventures relating to the development, manufacture, purchase, and sale of products, processes, and services covered by the licensed patent.

The license agreement will terminate on the expiration of the last-to-expire of the university’s issued licensed patents. If no further patents covered by the license agreement are issued, the license agreement would terminate in 2024. The university may terminate the agreement in the event of Asterias’ breach of the agreement. Asterias can terminate the agreement upon 60 days’ notice.

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Wistar License Agreement

OncoCyte has entered into a Sponsored Research Agreement (“SRA”), with Wistar pursuant to which Wistar investigators are conducting a multi-center patient study to assess gene expression patterns in blood cells of patients with malignant versus non-malignant lung disease. OncoCyte has agreed to provide funding for the research that Wistar is conducting under the SRA. OncoCyte has agreed to indemnify Wistar, certain related persons, and the principal investigator against liabilities, damages, losses and expenses due to claims by any third party which result or arise out of the SRA, or any licenses of Wistar inventions. OncoCyte exercised certain rights under the SRA to obtain a license under use certain patents, know-how and data belonging to Wistar, including technology and data developed under the SRA.

License Granted

OncoCyte has entered into a License Agreement with Wistar pursuant to which OncoCyte has obtained an exclusive, worldwide license under certain patents, and under certain know-how and data (“Technical Information”) belonging to Wistar, for use in the field of molecular diagnostics for lung cancer, including, but not limited to confirmatory, companion and recurrence diagnostics for any type of lung cancer with detection through whole blood, fractionated blood, plasma, serum and/or other biological samples (the “Licensed Field”).

OncoCyte has the right to grant sublicenses of the licensed patents and Technical Information. The sublicensee will be subject to Wistar’s approval, which will not be unreasonably withheld, if OncoCyte is not selling a “Licensed Product.” As used in the License Agreement, a Licensed Product means any product that cannot be made, used, or sold, or any service, process or method that cannot be performed or provided, without infringing at least one pending or issued valid claim under the licensed patents in a particular country, or that incorporates or is made, identified, developed, optimized, characterized, selected, derived or determined to have utility, in whole or in part, by the use or modification of any licensed patent or any technology or invention covered thereby, any licensed Technical Information, or any other Licensed Product.

Royalties, License Fees and Other Payment Obligations

OncoCyte has paid Wistar an initial license fee and will pay Wistar royalties on net sales, as defined in the License Agreement, of Licensed Products. The royalty rates will range from 3% to 5% depending upon the amount of cumulative net sales of Licensed Products. If OncoCyte is required to pay royalties to a third party in order to manufacture or sell a Licensed Product in a particular country, the amount of royalties payable to Wistar on net sales of the Licensed Product will be reduced by the amount of royalties paid to the third party, but subject to a maximum reduction of 50%. OncoCyte’s obligation to pay royalties to Wistar will terminate on a Licensed Product by-Licensed Product and country-by-country basis until the later of (i) the date a valid claim of a licensed patent covering the Licensed Product no longer exists, or (ii) the tenth (10th) anniversary of the first commercial sale of the Licensed Product in each country.

OncoCyte will pay Wistar a minimum annual royalty during each subsequent year, which in each case will be credited against total royalties due on net sales of Licensed Products during the year in which the minimum royalty is paid. OncoCyte will also be obligated to pay Wistar an annual license maintenance fee each year unless sales of at least one Licensed Product are initiated by January 1, 2018.

In addition to royalties on net sales, if OncoCyte grants any sublicense to the licensed patents or Technical Information, OncoCyte will pay Wistar a portion of any non-royalty sublicensing income that OncoCyte may receive from the sublicensee. Non-royalty sublicensing income will include any consideration received from a sublicensee for granting the sublicense, but excluding royalties on net sales of Licensed Products, the fair market value of any equity or debt securities that OncoCyte may sell to a sublicensee, and any payments OncoCyte receives from a sublicensee

for research of a Licensed Product that OncoCyte may conduct. OncoCyte also will pay Wistar (a) milestone payments upon the occurrence of certain milestone events in the development and commercialization of a Licensed Product, and (b) all past or ongoing costs incurred or to be incurred by Wistar, including government fees and attorneys' fees, in the course of prosecuting the licensed patents.

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Other Obligations

OncoCyt e has agreed to use commercially reasonable diligent efforts, directly or through sublicensees, to develop and commercialize Licensed Products and will provide Wistar with written plans for the development and commercialization of Licensed Products, and Wistar has the right to raise reasonable objections to those plans. OncoCyt e will also provide Wistar with annual reports on progress in developing, evaluating, testing, and commercializing Licensed Products. OncoCyt e has agreed that it or a sublicensee will commence commercial sale of a Licensed Product by a specified date. If sales of a Licensed Product do not commence by the specified date, OncoCyt e may purchase up to three one-year extensions of the deadline by paying Wistar a designated fee for the applicable extension.

OncoCyt e will indemnify Wistar and its trustees, managers, officers, agents, employees, faculty, affiliated investigators, personnel and staff (the “Indemnified Parties”), from and against any and all liability, loss, damage, action, claim or expense (including attorney’s fees) suffered or incurred by the Indemnified Parties due to claims which result from or arise out of (a) the License Agreement and the license granted by Wistar, and any sublicense granted by OncoCyt e pursuant to the License Agreement, (b) the development, use, manufacture, promotion, sale or other disposition of the licensed patents, licensed Technical Information or any Licensed Products, (c) the breach of any of OncoCyt e’s representations, warranties, or covenants in the License Agreement, or a breach of a sublicense by a sublicensee, or (d) the successful enforcement by an Indemnified Party of its indemnification rights under the License Agreement. This indemnification obligation shall apply to liabilities resulting from: (i) any product liability or other claim of any kind related to the use of a Licensed Product; (ii) any claim that the licensed patents or the design, composition, manufacture, use, sale or other disposition of any Licensed Product infringes or violates any patent, copyright, trademark or other intellectual property rights of any third party; or (iii) clinical trials or studies conducted by or on behalf of OncoCyt e or any sublicensee relating to the Licensed Products. Notwithstanding the foregoing, OncoCyt e will not be obligated to indemnify and hold harmless the Indemnified Parties from and against any liabilities that result from or arise out of an Indemnified Party’s gross negligence or willful misconduct.

Termination of the License Agreement

Wistar has the right to terminate the License Agreement, subject to certain notice and cure periods and force majeure delays in certain cases, if any of the following occur: (a) OncoCyt e fails to pay any amount payable to Wistar; (b) OncoCyt e materially breaches any covenant or agreement or any continuing representation or warranty contained in the License Agreement; (c) OncoCyt e becomes subject to certain bankruptcy or insolvency events, (d) OncoCyt e dissolves or ceases operations, (e) OncoCyt e or any of its affiliates or sublicensees or affiliates of any sublicensees challenges the validity, patentability, scope, construction, enforceability, non-infringement, or Wistar’s ownership of any issued patent comprising the licensed patents, or assists any third party in any such challenge; or (f) OncoCyt e fail to fulfill its product development and commercialization diligence obligations and related performance milestones.

OncoCyt e has the right to terminate the License Agreement, subject to a notice and cure period, if Wistar materially breaches the License Agreement. At any time after the second anniversary date of the License Agreement OncoCyt e may terminate the License Agreement, with or without cause, upon the passage of a specified period of time after giving Wistar written notice of termination.

Wistar’s Retained Rights to Certain Proposed Products

Wistar has reserved the right to (i) make, use, practice and further develop the licensed patents and Technical Information for educational, research, and other internal purposes; (ii) grant to any academic, government, research or non-profit institution or organization the right to make, use and practice the licensed patents or Technical Information for non-commercial research and educational purposes; and (iii) grant licenses under the Licensed Patents or Technical Information to any party for any field, product, service or territory other than the Licensed Products in the

Licensed Field.

In addition, if Wistar determines to develop or have developed an actual or potential Licensed Product that is for an application, product, sub-field or indication in the Licensed Field, but for which Wistar reasonably believes a Licensed Product is not being actively developed or commercialized by OncoCyte or by OncoCyte's affiliates or sublicensees, Wistar may give OncoCyte notice of the proposed product. If OncoCyte timely informs Wistar of OncoCyte's election to develop the proposed product, and if OncoCyte successfully negotiates a development plan and milestones for the proposed product, OncoCyte will be entitled to develop the proposed product as a Licensed Product under the License Agreement. If OncoCyte does not elect to develop the proposed product or does not reach agreement with Wistar for a development plan and milestones for the proposed product, Wistar may exclude the proposed product from the license under the License Agreement and may develop the proposed product itself or grant licenses to third parties under the licensed patents and Technical Information for the development and commercialization of the proposed product.

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Hadasit Research and License Agreement

Cell Cure Neurosciences has entered into an Amended and Restated Research and License Agreement with Hadasit under which it received an exclusive license to use certain of Hadasit's patented technologies for the development and commercialization for pluripotent stem cell-derived cell replacement therapies for retinal degenerative diseases. Cell Cure Neurosciences paid Hadasit 249,058 New Israeli Shekels as a reimbursement for patent expenses incurred by Hadasit, and pays Hadasit quarterly fees for research and product development services under a related Product Development Agreement.

If Cell Cure Neurosciences grants, subject to the terms of the Amended and Restated Research and License Agreement, a sublicense to any strategic partner comparable to Teva Pharmaceutical Industries Ltd. (a "Strategic Partner"), Cell Cure Neurosciences will pay Hadasit 30% of all sublicensing payments made by said Strategic Partner to Cell Cure Neurosciences, other than payments for research, reimbursements of patent expenses, loans or equity investments, provided that the minimum payments due to Hadasit in respect of amounts which constitute royalties based on sales of licensed products by the Strategic Partner, its affiliates or sublicensees shall not be less than 1.2% of the underlying net sales.

If Cell Cure Neurosciences does not grant a sublicense to a Strategic Partner but instead commercializes OpRegen® itself or sublicenses the Hadasit patents to a third party for the completion of development or commercialization of OpRegen®, Cell Cure Neurosciences will pay Hadasit a 5% royalty on sales of products that utilize the licensed technology. Cell Cure Neurosciences will also pay sublicensing fees ranging from 10% to 30% of any payments Cell Cure Neurosciences receives from sublicensing the Hadasit patents. Commencing in January 2017, Hadasit will be entitled to receive an annual minimum royalty payment of \$100,000 that will be credited toward the payment of royalties and sublicense fees otherwise payable to Hadasit during the calendar year. If Cell Cure Neurosciences or a sublicensee other than a Strategic Partner paid royalties during the previous year, Cell Cure Neurosciences may defer making the minimum royalty payment until December and will be obligated to make the minimum annual payment to the extent that royalties and sublicensing fee payments made during that year are less than \$100,000.

If Cell Cure Neurosciences does not grant a sublicense to a Strategic Partner and Cell Cure Neurosciences or a sublicensee (other than a Strategic Partner) conducts clinical trials of OpRegen®, Hadasit will be entitled to receive certain payments from Cell Cure Neurosciences upon the first attainment of certain clinical trial milestones in the process of seeking regulatory approval to market a product developed by Cell Cure Neurosciences using the licensed patents. Hadasit will receive \$250,000 upon the completion of the enrollment of patients in the first Phase I clinical trial, \$250,000 upon the submission of a report summarizing the Phase II clinical trial data to a regulatory agency as part of the approval process, and \$1 million upon the enrollment of the first patient in the first Phase III clinical trial. These milestone payments are creditable by Cell Cure Neurosciences against sublicensing receipts that are payable to Hadasit at the time of each milestone payment for said milestone payment, except that the \$1.0 million milestone payment shall only be creditable by Cell Cure Neurosciences if it received sublicensing receipts in excess of the amount of \$50 million.

The Hadasit license agreement will automatically expire upon the later of (i) the expiration of all of the licensed patents or (ii) 15 years following the first sale of a product developed using a licensed patent on a country-by-country and product-by-product basis. After expiration of the license agreement, Cell Cure Neurosciences will have the right to exploit the Hadasit licensed patents without having to pay Hadasit any royalties or sublicensing fees. Either party may terminate the license agreement if the other party commits a breach or default in the performance of its obligations under the agreement and fails to cure the breach or default within the permitted cure periods.

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Cornell University

During August, 2011, we entered into a License Agreement with Cornell University for the worldwide development and commercialization of technology developed at Weill Cornell Medical College for the differentiation of pluripotent stem cells into vascular endothelial cells. The technology may provide an improved means of generating vascular endothelial cells on an industrial scale, and will be utilized by us in diverse products, including those under development at our subsidiary ReCyte Therapeutics to treat age-related vascular disease.

Our license to use the technology and patent rights is worldwide and exclusive and permits us to use the licensed technology and patents rights for the fields of cell therapy for age- and diabetes-related vascular diseases and cancer therapy. The license also covers (i) products utilizing human vascular or vascular forming cells for the purpose of enhancing the viability of the graft of other human cells, and (ii) cell-based research products. We also have a non-exclusive right to use any related technology provided by Cornell within the same fields of use, and non-exclusive rights with respect to any non-cell-based products for the research market not covered by the licensed patent rights.

We have the right to permit our subsidiaries and other affiliates to use the licensed patent rights and technology, and we have the right to grant sublicenses to others.

Cornell will be entitled to receive an initial license fee and annual license maintenance fees. The obligation to pay annual license maintenance fees will end when the first human therapeutic license product is sold by us or by any of our affiliates or sublicensees. A “licensed product” includes any service, composition or product that uses the licensed technology, or is claimed in the licensed patent rights, or that is produced or enabled by any licensed method, or the manufacture, use, sale, offer for sale, or importation of which would constitute an infringement, an inducement to infringe, or contributory infringement of any pending or issued claim within the patent rights licensed to us. A “licensed method” means any method that uses the licensed technology, or is claimed in the patent rights licensed to us, the use of which would constitute an infringement, an inducement to infringe, or contributory infringement of any pending or issued claim within the patent rights licensed to us.

We will pay Cornell a milestone payment upon the achievement of a research product sales milestone amount, and we will make milestone payments upon the attainment of certain FDA approval milestones, including (i) the first Phase II clinical trial dosing of a human therapeutic licensed product, (ii) the first Phase III clinical trial dosing of a human therapeutic licensed product, (iii) FDA approval of first human therapeutic licensed product for age-related vascular disease, and (iv) FDA approval of the first human therapeutic licensed product for cancer.

We will pay Cornell royalties on sales of licensed products by ourselves and our affiliates and sublicensees, and we will share with Cornell a portion of any cash payments, other than royalties, that we receive for the grant of sublicenses to non-affiliates. We will also reimburse Cornell for costs related to the patent applications and any patents that may issue that are covered by our license.

We will provide Cornell with periodic reports of progress made in our research and development and product commercialization programs, and in those programs conducted by our affiliates and sublicensees, using the licensed patents and technology. We and our affiliates and sublicensees will be required to keep accurate records of the use, manufacture and sale of licensed products, and of sublicense fees received. Cornell has the right to audit those records that we and our affiliates maintain.

The license will expire on the later of (i) the expiration date of the longest-lived licensed patent, or (ii) on a country-by-country basis, on the twenty-first anniversary of the first commercial sale of a licensed product. We have the right to terminate the License Agreement at any time and for any reason upon ninety (90) days written notice to Cornell. Cornell may terminate our license if we fail to perform, or if we violate, any term of the License Agreement,

and we fail to cure that default within thirty (30) days after written notice from Cornell.

Cornell also may terminate the license or convert the exclusive license to a non-exclusive license if we fail to meet any of the following requirements: (i) diligently proceed with the development, manufacture and sale of licensed products; (ii) annually spend certain specified dollar amounts for the development of licensed products; (iii) submit an investigational new drug application covering at least one licensed product to the FDA within eight (8) years after the effective date of the License Agreement; (iv) initiate preclinical toxicology studies for at least one licensed product within six (6) years after the effective date of the License Agreement; (v) market at least one therapeutic licensed product in the U.S. within twelve (12) months after receiving regulatory approval to market the licensed product; or (vi) market at least one cell-based licensed product for the research market in the U.S. within twelve (12) months after the effective date of the License Agreement. We may fulfill the obligations described in (i) through (vi) through our own efforts or through the efforts of our affiliates and sublicensees.

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Termination of the License Agreement by us or by Cornell or upon expiration will not relieve us of our obligations to make payments of fees owed at the time of termination, and certain provisions of the License Agreement, including the indemnification and confidentiality provisions, will survive termination. We may continue to sell all previously made or partially made licensed product for a period of one hundred and twenty (120) days after the License Agreement terminates, provided that the reporting and royalty payment provisions of the License Agreement will continue to apply to those sales.

We have agreed to indemnify Cornell; Cornell Research Foundation, Inc.; Howard Hughes Medical Institute; and their officers, trustees, employees, and agents, the sponsors of the research that led to the licensed patent rights; and the inventors and their employers, against any and all claims, suits, losses, damage, costs, fees, and expenses resulting from or arising out of exercise of the licenses and any sublicenses under the License Agreement. The indemnification will include, but not be limited to, patent infringement and product liability. We have also agreed to provide certain liability insurance coverage for Cornell and Howard Hughes Medical Institute.

Cornell and Howard Hughes Medical Institute will retain the right to use the licensed technology and patent rights for their own educational and research purposes. Cornell may also permit other nonprofit institutions to use the technology and patent rights for educational and research purposes.

Icahn School of Medicine at Mount Sinai

During May 2014, LifeMap Solutions entered into a Co-Development and Option Agreement, which was amended during March 2015 (the “Mt. Sinai Agreement”) with the Icahn School of Medicine at Mount Sinai, a nonprofit education corporation (“Mount Sinai”), pursuant to which LifeMap Solutions and Mount Sinai have agreed to work cooperatively to develop internet, web-based, mobile user or consumer software products to provide users with information that may potentially aid them in improving lifestyle and healthcare decisions and outcomes.

LifeMap Solutions and Mount Sinai will license to each other, on a non-exclusive, royalty free basis, certain “background” intellectual property for joint use in product development. LifeMap Solutions will pay Mount Sinai for the use of Mount Sinai personnel based on their direct salaries plus an overhead charge, but Mount Sinai has agreed to waive collection of the first \$1.0 million of overhead charges. LifeMap Solutions will have an option to acquire a world-wide license to use Mount Sinai’s background intellectual property and other intellectual property developed by Mount Sinai alone or jointly with LifeMap Solutions in the joint development project for the purpose of developing and commercializing the product.

License Terms

The terms of the license agreement that will be executed if LifeMap Solutions exercises its option under the Mt. Sinai Agreement (the “Mt. Sinai License Agreement”) are subject to negotiation by the parties, but will include certain provisions specified in the Mt. Sinai Agreement.

The license will be exclusive with respect to intellectual property developed by Mount Sinai alone or jointly with LifeMap Solutions as part of the project, but will be non-exclusive as to Mount Sinai’s (a) background technology and know-how relating to development of software, algorithms, and databases capable of analyzing complex data sets and generating predictive models, (b) software code that pertains to analysis of genetic data sets or compiling data sets, (c) electronic medical record data, and (d) algorithms and data bases that incorporate certain genetic information, clinical data and other information of individuals relating to human disease, health or wellness.

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LifeMap Solutions will pay Mount Sinai a royalty on Net Sales of the product or “Licensed Services” by LifeMap Solutions and its affiliates and sublicensees. Net Sales means the gross amount, prior to any discounts or other list price reductions, invoiced by LifeMap Solutions and its affiliates and sublicensees for sales of the product or Licensed Services for end use or consumption by third parties, less (a) normal and customary quantity and/or cash discounts and sales returns and allowances, including, without limitation, those granted on account of price adjustments, billing errors, rejected goods, damaged goods, returns, rebates actually allowed and taken, administrative or other fees or reimbursements of similar payments to wholesalers or other distributors, buying groups, or other institutions; (b) rebates or similar payments made with respect to sales paid for by any governmental or regulatory authority, (c) customs or excise duties or other duties directly imposed and related to the sales making up the gross invoice amount; (d) sales and other taxes and duties directly related to the sale, to the extent that such items are included in the gross invoice price; and (e) freight, postage, shipping, and insurance expenses separately identified in the invoice.

“Licensed Service” means any service, including without limitation database access, provided by LifeMap Solutions, its distributors, or sublicensees to a third party in exchange for consideration where the service makes use of the product or otherwise exploits or monetizes certain intellectual property licensed by Mount Sinai.

LifeMap Solutions’ obligation to pay royalties will expire on a product-by-product or Licensed Service-by-Licensed Service and country-by-country basis, from first commercial sale or commercial license, whichever comes first, until the later of: (a) expiration of the last patent rights covering the product or Licensed Service in a country; (b) expiration of any market exclusivity period granted by a regulatory agency with respect to the product or Licensed Service in a country; or (c) LifeMap Solutions’ final discontinuation of sale or commercial licensing of a product or Licensed Service in a country.

In addition to royalties on Net Sales, LifeMap Solutions will pay Mount Sinai a percentage of any consideration received by LifeMap Solutions from its sublicensees and distributors of the product. Any non-cash consideration received by LifeMap Solutions will be valued at its fair market value as of the date of receipt. The percentage of the consideration to be paid to Mount Sinai will depend upon the stage of development of the product at the time the applicable sublicense or distributor agreement is signed.

LifeMap Solutions will pay Mount Sinai up to 5% of the then current equity value of LifeMap Solutions at the time of a “Significant Transaction.” The percentage to be paid is subject to dilution based on future investment in LifeMap Solutions and the amount of personnel cost overhead charges waived by Mount Sinai under the Mt. Sinai Agreement. The term “Significant Transaction” will mean the first to occur of a single transaction, or series of related transactions, consisting of or resulting in any of the following: (i) an assignment, other than to LifeMap Sciences, of the definitive license agreement; (ii) an initial public offering of securities by LifeMap Solutions (or its successor) or other transaction resulting in any of LifeMap Solutions’ securities being traded on a nationally recognized stock exchange or automated quotation system; (iii) a sale, license or other disposition of all or substantially all of LifeMap Solutions’ assets; or (iv) a reorganization, consolidation or merger of LifeMap Solutions, or sale or transfer of the securities of LifeMap Solutions, where the holders of LifeMap Solutions’ outstanding voting securities before the transaction beneficially own less than fifty percent (50%) of the outstanding voting securities, or hold less than fifty percent (50%) of the voting power of the voting security holders of the surviving entity after the transaction. A Significant Transaction shall not be deemed to occur as a result of a bona fide, arm’s-length equity financing for cash in which LifeMap Solutions issues securities (other than through an initial public offering described in clause (ii) above) representing more than fifty percent (50%) of the voting power of its security holders to venture capital or other similar professional investors who do not actively manage day-to-day operations of LifeMap Solutions.

The Mt. Sinai License Agreement will require LifeMap Solutions to use reasonable commercial efforts to develop and commercialize the products and to meet certain diligence milestones and timelines, which are expected to include (a) demonstrating a specified level of capital investment to fund product development, (b) production of a product prototype, (c) launch of a beta stage version of the product, and (c) commercial launch of the product to the public. If

LifeMap Solutions fails to attain an agreed diligence milestone by the applicable deadline, Mount Sinai will be entitled to convert the exclusive license to a non-exclusive license, provided that any delays caused by Mount Sinai will extend the milestone achievement deadline.

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LifeMap Solutions will reimburse Mount Sinai for all reasonable patent and licensing costs incurred prior to the effective date of the definitive license agreement in connection with the licensed patent rights and certain other Mount Sinai technology and background intellectual property. LifeMap Solutions will also pay all reasonable attorney's fees, expenses, official fees, and other charges incident to the preparation, prosecution, and maintenance of licensed patent rights.

Termination of the Agreement

Either party may terminate the Mt. Sinai Agreement if the services of the principal investigator become unavailable to Mount Sinai for any reason and a member of Mount Sinai's faculty acceptable to both Mount Sinai and LifeMap Solutions is not designated as the replacement principal investigated within the time allotted by the Mt. Sinai Agreement.

Either party may terminate the Mt. Sinai Agreement at any time after the second anniversary of the signing of the agreement, upon ninety (90) days' prior written notice. LifeMap Solutions may terminate the Mt. Sinai Agreement, at any time after the first anniversary of the agreement, upon ninety (90) days' prior written notice to Mount Sinai if LifeMap Solutions determines that the product is not a commercially viable product.

Either LifeMap Solutions or Mount Sinai may terminate the Mt. Sinai Agreement upon written notice to the other party if the other party breaches any of the material terms or conditions of the agreement and fails to cure the breach within ninety (90) days after receiving written notice of the breach, except that in a breach is incurable, the non-breaching party may terminate the agreement upon fifteen (15) days' written notice to the breaching party.

Mount Sinai may terminate the Mt. Sinai Agreement upon thirty (30) days' written notice to LifeMap Solutions should any federal law require regulatory controls, compliance, or other protections for direct-to-consumer genetic testing that Mount Sinai is unable to reasonably comply with; provided that, if reasonable, Mount Sinai shall first cease the noncompliant services and/or activities; and if LifeMap Solutions in its sole discretion, determines that ceasing the non-compliant activity would materially impact the Mt. Sinai Agreement, LifeMap Solutions may terminate the agreement upon ten (10) days' notice to Mount Sinai. If any state requires regulatory controls, compliance, or other protections for direct-to-consumer genetic testing that Mount Sinai is unable to reasonably comply with, Mount Sinai may terminate services and activities with respect to that state.

Either party may terminate the Mt. Sinai Agreement if it receives a notice from a third party claiming that the party's activities under the agreement infringe the third party's intellectual property rights; and, after investigation of the claim of infringement, the party determines that there exists a likely infringement and that it cannot cure the infringement within ninety (90) days or perform its obligations under the agreement without engaging in infringing activities.

Asterias Royalty Agreement with Geron

In connection with its acquisition of stem cell assets from Geron, Asterias entered into a Royalty Agreement with Geron pursuant to which Asterias agreed to pay Geron a 4% royalty on net sales (as defined in the Royalty Agreement), by Asterias or any of its affiliates or sales agents, of any products that Asterias develops and commercialize that are covered by the patents Geron contributed to Asterias. In the case of sales of such products by a person other than Asterias or one of its affiliates or sales agents, Asterias will be required to pay Geron 50% of all royalties and cash payments received by it or by its affiliate in respect of a product sale. Royalty payments will be subject to proration in the event that a product covered by a patent acquired from Geron is sold in combination with another product that is not covered by a patent acquired from Geron. The Royalty Agreement will terminate at the expiration or termination date of the last issued patent contributed by Geron under the Royalty Agreement. We estimate that the latest patent expiration date will be 2029.

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Clinical Trial and Option Agreement with Cancer Research United Kingdom

During September 2014, Asterias entered into the CRUK Agreement with CRUK and CRT, a wholly-owned subsidiary of CRUK, pursuant to which CRUK has agreed to fund Phase I/IIa clinical development of AST-VAC2. Asterias will, at their own cost, complete process development and manufacturing scale-up of the AST-VAC2 manufacturing process and will transfer the resulting cGMP-compatible process to CRUK. CRUK will, at its own cost, manufacture clinical grade AST-VAC2 and will carry out the Phase I/IIa clinical trial of AST-VAC2 in cancer patients in both resected early-stage and advanced forms of lung cancer. Asterias will have an exclusive first option to obtain a license to use the data from the clinical trial. If Asterias exercises that option Asterias will be obligated to make payments upon the execution of the License Agreement, upon the achievement of various milestones, and then royalties on sales of products, and, if Asterias sublicenses product development or commercialization rights to a third party, Asterias would pay CRT a share of any sublicense revenues we receive from the third party, with CRT's share varying from a high of 40% in the case of a sublicense entered into prior to commencement of a Phase II clinical trial, to substantially lower rates in the case of a sublicense entered into at various later stages of clinical development but prior to completion of a Phase III clinical trial, and as low as 7.5% in the case of a sublicense entered into after completion of a Phase III clinical trial. In connection with the CRUK Agreement, Asterias sublicensed to CRUK for use in the clinical trials and product manufacturing process certain patents that have been licensed or sublicensed to by third parties. Asterias would also be obligated to make payments to those licensors and sublicensors upon the achievement of various milestones, and then royalties on sales of products if AST-VAC2 is successfully developed and commercialized.

If Asterias declines to exercise its option, CRT will then have an option to obtain a license to use Asterias' intellectual property relating to AST-VAC2 to continue the development and commercialization of AST-VAC2 and related products for which Asterias will be entitled to receive a share of the revenue relating to development and partnering proceeds. The CRT's option will be exercisable by CRT for four months from when the Asterias' option expires.

The CRUK Agreement will expire upon the earliest of (i) the date Asterias obtains a license to use the clinical data pursuant to an exercise of its option, (ii) the date CRT obtains a license to continue the development and commercialization of AST-VAC2 pursuant to an exercise of its option and (iii) the expiration of both the Asterias' option and the CRT's option. Notwithstanding the foregoing, any party may terminate the CRUK Agreement prior to its expiration for events including (i) a party materially breaches the agreement and such breach is not cured within 60 days after the non-breaching party delivers written notice, (ii) any party is insolvent or liquidated or (iii) if regulatory approval of the clinical trial is not obtained within two years after the parties complete the technology transfer phase of the agreement, or if regulatory approval is revoked, withdrawn or otherwise terminated, or if a regulatory authority orders a halt or hold on the clinical trial for more than 18 months. In addition, CRUK will have the right to terminate the CRUK Agreement under certain other circumstances.

The CRUK Agreement contains customary representations, warranties and covenants from Asterias and CRUK, as well as customary provisions relating to indemnity, confidentiality and other matters.

Services Agreement with Cell Therapy Catapult Services Limited

Asterias Biotherapeutics has entered into a Services Agreement (the "Services Agreement") with Cell Therapy Catapult Services Limited ("Catapult"), a research organization specializing in the development of technologies which speed the growth of the cell and gene therapy industry. Under the Services Agreement, Catapult will license to Asterias, certain background intellectual property and will develop a scalable manufacturing and differentiation process for Asterias' human embryonic stem cell derived AST-VAC2 allogeneic (non-patient specific) dendritic cancer vaccine development program. In consideration for the license and Catapult's performance of services, Asterias agreed to make aggregate payments of up to GBP £4,350,000 over the next five years. At the option of Asterias, up to GBP £3,600,000 of such payments may be settled in shares of Asterias Series A Common Stock.

The Services Agreement may be terminated by Asterias for any reason upon 60 days prior written notice. Catapult may terminate the Services Agreement on 60 days prior written notice if it encounters a technical issue that would prevent it from completing the services at all or without obtaining additional resources, or if the estimated time and cost of completing the services will be exceeded and Catapult and Asterias do not reach agreement on revised time and cost terms. Catapult may terminate the Services Agreement in the event Asterias fails to pay any amount due under the Services Agreement 30 days after Catapult makes a written demand for payment. In addition, a non-breaching party may terminate the Services Agreement upon the occurrence a material breach that is not remedied within 30 days. Either party may terminate the Services Agreement in the event the other party becomes subject to insolvency, receivership, liquidation, or a similar event.

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Major Customers

During 2015, most of our royalty revenues were primarily from product sales under a non-exclusive license agreement between Asterias and GE Healthcare in the amount of \$334,000 and with Stem Cell Technologies, Inc. in the amount of \$150,000. During 2015, we also received royalty revenues generated through sales of Hextend® by Hospira in the US in the amount of \$139,000. Hospira was purchased by Pfizer, Inc. in February 2015.

During 2014 and 2013, most of our royalty revenues was generated through sales of Hextend® by Hospira in the U.S. During 2014, we also received royalty revenues from product sales under a non-exclusive license agreement between Asterias and Stem Cell Technologies, Inc.

During 2015, 2014 and 2013 we also earned license fees from CJ Health and during 2014 and 2013, from Summit Pharmaceuticals International Corporation (“Summit”). We received the license fees from CJ Health and Summit during the years 2003 through 2005. Full recognition of the revenues derived from those license fees was deferred and revenues have been recognized over the lives of the respective contracts, which had been estimated to last until approximately 2019 based on the current expected life of the governing patent covering our products in Korea and Japan. However, we recognized the unamortized balance of the Summit license fees during the fourth quarter of 2014 as a result of the termination of our license agreements with Summit. The following table shows revenues paid by customers that were recognized during the past three fiscal years and that accounted for 5% or more of our total annual revenues.

Licensee	% of Total Revenues for the Year Ending December 31,		
	2015	2014	2013
GE HealthCare	5%	-%	-%
Hospira	2%	10%	11%
CJ Health	-%	3%	8%
Stemcell Technologies	2%	9%	-%
Summit	-%	-%	35%

Royalty Revenues and License Fees by Geographic Area

The following table shows the source of our 2015, 2014, and 2013 royalty and license fee revenues by geographic areas, based on the country of domicile of the licensee (in thousands):

Geographic Area	Revenues for Year Ending December 31,		
	2015	2014	2013
Domestic	2,056	\$1,519	\$1,607
Asia	20	51	978
Total Revenues	2,076	\$1,570	\$2,585

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Manufacturing

Facilities Required—Stem Cell Products

We lease approximately 30,795 square feet of rentable space in two buildings located in an office park setting in Alameda, California. We plan to build a small cGMP compliant suite for the purpose of producing cell banks and small production runs of pluripotent stem cells and PureStem® cell lines. Our subsidiaries, OncoCyte, OrthoCyte, and ReCyte Therapeutics are also conducting their research and development activities at our Alameda facility.

Cell Cure Neurosciences leases approximately 1,075 square meters of office, laboratory, warehousing and cGMP production space located at Hadassah Ein Kerem, in Jerusalem, Israel.

Asterias leases a 44,000 square foot facility in Fremont, California at which it has constructed a cGMP compliant facility for the production of its product candidates.

BioTime leases an office and research facility located in San Diego, California that is used by Ascendance for the development of new differentiation and cellular reprogramming research products. The lease covers approximately 1,267 square feet of space.

Facilities Required—Laboratory Diagnostic Tests

OncoCyte plans to construct a CLIA compliant laboratory at our Alameda facility for the performance of any cancer diagnostic tests that it may successfully develop and commercialize. OncoCyte will be required to hold certain federal, state and local licenses, certifications and permits to operate its diagnostic test laboratory, including certification under CLIA, under the laws of the states from which it receives blood or urine samples for testing. See “Government Regulation -- Clinical Laboratory Improvement Amendments of 1988 and State Regulation.”

Facilities Required—Plasma Volume Expanders

Hospira manufactures Hextend® for use in the North American market, and CJ Health manufactures Hextend® for use in South Korea. Hospira and CJ Health have the facilities to manufacture Hextend® and our other products in commercial quantities. If Hospira and CJ Health choose not to manufacture and market other BioTime products, other manufacturers will have to be identified that would be willing to manufacture products for us or any licensee of our products as we do not have facilities to manufacture our plasma volume expander products in commercial quantities, or under cGMP.

Raw Materials—Plasma Volume Expanders

Although most ingredients in the products we are developing are readily obtainable from multiple sources, we know of only a few manufacturers of the hydroxyethyl starches that serve as the primary drug substance in Hextend®. Hospira and CJ Health presently have a source of supply of the hydroxyethyl starch used in Hextend® and have agreed to maintain a supply sufficient to meet market demand for Hextend® in the countries in which they market the product. We believe that we will be able to obtain a sufficient supply of starch for our needs in the foreseeable future, although we do not have supply agreements in place. If for any reason a sufficient supply of hydroxyethyl starch could not be obtained, a licensee would have to acquire or obtain by contract the use of a manufacturing facility and the technology to produce the hydroxyethyl starch according to cGMP if the licensee elects to continue manufacturing Hextend®.

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Marketing

Ascendance Assay and Stem Cell Research Products

Ascendance markets its drug assay tests for use in drug-development and safety-testing of products in the pharmaceutical and chemical industries, under the brand names HepatoPac® and HepatoMune®.

Ascendance also markets products for use in stem cell research, including PureStem® embryonic progenitors, research grade HyStem® hydrogel matrix products, ESI pluripotent stem cell lines, and differentiation and stem cell reprogramming products. These research products are being offered to researchers at universities and other institutions, at companies in the bioscience and biopharmaceutical industries, and at other companies that provide research products to companies in those industries.

Online Database Products

LifeMap Sciences sells subscriptions to its database products to biotech and pharmaceutical companies worldwide. The LifeMap Discovery® data base provides access to available cell-related information and resources necessary to improve stem cell research and development of therapeutics based on regenerative medicine.

Plasma Volume Expanders

Hextend® is being distributed in the U.S. by Hospira and in South Korea by CJ Health under exclusive licenses from us. Hospira also has the right to obtain licenses to manufacture and sell our other plasma volume expander products.

Because Hextend® is a surgical product, sales efforts must be directed to physicians and hospitals. The Hextend® marketing strategy is designed to reach its target customer base through sales calls, through an advertising campaign focused on the use of a plasma-like substance to replace lost blood volume, and on the ability of Hextend® to support vital physiological processes.

Hextend® competes with other products used to treat or prevent hypovolemia, including albumin, generic 6% hetastarch solutions, and crystalloid solutions. The competing products have been commonly used in surgery and trauma care for many years, and in order to sell Hextend®, physicians must be convinced to change their product loyalties. The market price of albumin has declined and generic 6% hetastarch solutions sell at low prices, which has caused Hospira and CJ Health to lower the prices at which they sell Hextend®.

In addition to price competition, sales of Hextend® have been adversely affected if 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.

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Therapeutic Products and Medical Devices

Because our planned therapeutic products and medical devices are still in the research and development stage, we will not initially need to have our own marketing personnel. If we or our subsidiaries are successful in developing marketable therapeutic products and medical devices we will need to build our own marketing and distribution capability for those products, which would require the investment of significant financial and management resources, or we and our subsidiaries will need to find collaborative marketing partners, independent sales representatives, or wholesale distributors for the commercial sale of those 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. This means that our gross profit from product sales may be less than would be the case if we were to sell our products directly to end users at retail prices through our own sales force. On the other hand, selling to distributors or through independent sales representatives would allow us to avoid the cost of hiring and training our own sales employees. There can be no assurance we will 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.

Laboratory Diagnostic Tests

Following CLIA certification of its laboratory and diagnostic tests, OncoCyte will market its diagnostic tests directly to health care providers working in the areas of cancer for which OncoCyte develops liquid biopsy tests. The health care providers will collect blood samples or send patients to laboratories to have blood or urine samples collected. The blood or urine samples will be sent to OncoCyte's CLIA laboratory in Alameda California, either by the health care provider or the laboratory, where the sample will be run through an assay and a gene expression classifier to determine a binary result, either benign or suspicious. That result will be presented to the physician ordering the procedure in a standardized report. OncoCyte expects to ramp up sales and marketing teams in coordination with progress in the development of its diagnostic tests and over time will continue to grow its sales, market access and marketing organizations to increase the awareness and utilization of its diagnostic tests.

Patents and Trade Secrets

We rely primarily on patents and contractual obligations with employees and third parties to protect our proprietary rights. We have sought, and intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the U.S. and certain foreign countries. There can be no assurance that any of our patents will guarantee protection or market exclusivity for our products and product candidates. We also use license agreements both to access technologies developed by other companies and universities and to convey certain intellectual property rights to others. Our financial success will be dependent in part on our ability to obtain commercially valuable patent claims and to protect our intellectual property rights and to operate without infringing upon the proprietary rights of others.

As of February 27, 2016, we owned or controlled or licensed directly or through our subsidiaries approximately 820 patents and pending patent applications worldwide including more than 230 issued or pending U.S. patents or patent applications. We also licensed over 140 patents and applications from WARF.

Our patents and patent applications are directed to compositions of matter, formulations, methods of use and/or methods of manufacturing, as appropriate. In addition to patenting our own technology and that of our subsidiaries, we and our subsidiaries have licensed patents and patent applications for certain stem cell technology, hEPC, and hES cell lines, diagnostic markers, hydrogel technology, and other technology from other companies. See "Licensed Stem Cell Technologies and Stem Cell Product Development Agreements."

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The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal and factual questions. Our business could be negatively impacted by any of the following:

- the claims of any patents that are issued may not provide meaningful protection, may not provide a basis for commercially viable products or may not provide us with any competitive advantages;
- our patents may be challenged by third parties;
- others may have patents that relate to our technology or business that may prevent us from marketing our product candidates unless we are able to obtain a license to those patents;
- the pending patent applications to which we have rights may not result in issued patents;
- we may not be successful in developing additional proprietary technologies that are patentable.

In addition, others may independently develop similar or alternative technologies, duplicate any of our technologies and, if patents are licensed or issued to us, design around the patented technologies licensed to or developed by us. Moreover, we could incur substantial costs in litigation if we have to defend ourselves in patent lawsuits brought by third parties or if we initiate such lawsuits

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 parthenogenetically 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 that date are no longer automatically excluded from patentability under Article 53 (a) EPC and Rule 28(c) EPC.

The United States Supreme Court’s decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics* may limit OncoCyte’s ability to obtain patent protection on diagnostic methods that merely recite a correlation between a naturally occurring event and a diagnostic outcome associated with that event. OncoCyte’s cancer diagnostic tests are based on the presence of certain genetic markers for a variety of cancers. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court ruled that patent protection is not available 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. The claims in the contested patents that were the subject of that decision were directed to measuring the serum level of a drug metabolite and adjusting the dosing regimen of the drug based on the metabolite level. The Supreme Court said that a patent claim that merely claimed a correlation between the blood levels of a drug metabolite and the best dosage of the drug was not patentable subject matter because it did no more than recite a correlation that occurs in nature.

In *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court ruled that the discovery of the precise location and sequence of certain genes, mutations of which can dramatically increase the risk of breast and ovarian cancer, was not patentable. Knowledge of the gene location and sequences was used to determine the genes’ typical nucleotide sequence, which, in turn, enabled the development of medical tests useful for detecting mutations in these genes in a particular patient to assess the patient’s cancer risk. But the mere discovery of an important and useful gene did not render the genes patentable as a new composition of matter.

The United States Patent and Trademark Office (the “USPTO”) has issued interim guidelines in light of the Supreme Court decisions indicating that process claims having a natural principle as a limiting step will be evaluated to

determine if the claim includes additional steps that practically apply the natural principle such that the claim amounts to significantly more than the natural principle itself. Because the diagnostic tests that OncoCyte is developing combine an innovative methodology with newly discovered compositions of matter, OncoCyte is hopeful that this Supreme Court decision will not preclude the availability of patent protection for OncoCyte's diagnostic tests.

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Patents Used in Our Stem Cell Business

The patents Asterias acquired from Geron and that have been licensed to Asterias by assignment of third party licenses have been issued in certain key countries and will expire at various times.

Oligodendrocyte progenitor cells: The patent rights relevant to oligodendrocyte progenitor cells include rights licensed from the University of California and various developed patent families covering the growth of hES cells and their differentiation into neural cells. There are issued patents in the United States, Australia, Canada, China, United Kingdom, Japan, Singapore and Israel. The expiration dates of these patents range from 2023 to 2029.

Cardiomyocytes: The patent rights relevant to cardiomyocytes include various patent families covering the growth of hES cells and their differentiation into cardiomyocytes. There are issued patents in the United States, Australia, Canada, China, United Kingdom, Hong Kong, Korea, Japan, India, Singapore and Israel. The expiration dates of these patents range from 2022 to 2029.

Pancreatic islet cells: The patent rights relevant to pancreatic islet cells include various patent families covering the growth of hES cells and their differentiation into pancreatic islet cells. There are issued patents in the United States, Australia, Canada, United Kingdom, Hong Kong, Korea, Japan, China, Singapore and Israel. The expiration dates of these patents are in 2022 to 2028.

Hepatocytes: The patent rights relevant to hepatocytes include various patent families covering the growth of hES cells and their differentiation into hepatocytes. There are issued patents in the United States, Australia, Canada, United Kingdom, Korea, India, Singapore and Israel. The expiration dates of these patents are in 2020 to 2029.

Neural cells: The patent rights relevant to neural cells include various patent families covering the growth of hES cells and their differentiation into neural cells. There are issued patents in the United States, Australia, Canada, United Kingdom, Japan, China, Hong Kong, India, Korea, Singapore and Israel. The expiration dates of these patents are in 2020 to 2023.

Hematopoietic cells: The patent rights relevant to hematopoietic cells include rights licensed from certain third parties and various patent families covering the growth of hES cells and their differentiation into hematopoietic cells. There are issued patents in the United States, Australia, United Kingdom, Singapore and Israel. The expiration dates of these patents are in 2022 to 2029.

Osteoblasts: The patent rights relevant to osteoblasts include various patent families covering the growth of hES cells and their differentiation into osteoblasts. There are issued patents in the Australia, United Kingdom, India, Singapore and Israel. The expiration dates of these patents are in 2022.

Chondrocytes: The patent rights relevant to chondrocytes include various patent families covering the growth of hES cells and their differentiation into chondrocytes. There are issued patents in the United States, Australia, Canada, Korea, Singapore and Israel. The expiration dates of these patents are in 2022 to 2023.

Dendritic cells: The patent rights relevant to dendritic cells include rights licensed from third parties and various patent families covering the growth of hES cells and their differentiation into dendritic cells. There are issued patents in the United States, Australia, Europe, Canada, China, Hong Kong and Japan. The expiration dates of these patents range from 2019 to 2025.

Platform patents: The platform patent rights include various patent families covering the growth of hES cells. There are issued patents in the United States, Australia, Canada, United Kingdom, Hong Kong, China, India, Japan, Singapore and Israel. The expiration dates of these patents range from 2018 to 2030.

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ViaCyte Patent Interference Proceedings

During May 2014, Asterias entered into a settlement agreement with ViaCyte, Inc. (“ViaCyte”) concerning certain litigation in the United States District Court for the Northern District of California (Civil Action No. C12-04813) seeking the reversal of two adverse determinations by the United States Patent and Trademark Office with respect to two patent applications in U.S. Patent Interference 105,734, involving U.S. patent 7,510,876 (ViaCyte) and U.S. patent application 11/960,477 (Geron), and U.S. Patent Interference 105,827 involving U.S. patent 7,510,876 (ViaCyte) and U.S. patent application 12/543,875 (Geron), along with four Opposition Proceedings pending before the Australian Patent Office pertaining to priority rights and the validity of each party’s patents relating to endodermal precursor cells. Under the terms of the settlement agreement, the parties granted to each other a royalty free, fully paid license to each other’s technology relating to endoderm lineage cells including definitive endoderm and gut endoderm cells, only to the extent necessary to allow the licensee to make, use, sell, offer for sale, or import endodermal lineage cells. The Asterias patents that were licensed to ViaCyte in the settlement include US Patent Application No 11/262-633. The ViaCyte patents that were licensed to us in the settlement included US Patent Application Nos. 11/021,618, 12/093,590, 10/584,338, 11/165,305, 11/317,387, and 11/860,494.

Patents Used by OncoCyt

The OncoCyt diagnostic portfolio includes 13 patent families owned by OncoCyt with claims directed to compositions of matter and methods useful for detection of breast, bladder, colon, pancreatic, ovarian, and thyroid cancers using specific biomarkers or a panel of specific biomarkers. Patents are pending in various jurisdictions, including the United States, Europe, Australia, Canada, China, Hong Kong, Japan and Republic of Korea, with projected expiration dates ranging from 2032 to 2036. Additionally, OncoCyt has one issued patent in Australia, with claims directed to a method of detecting bladder cancer; and one accepted patent application in Australia, with claims directed to a method of detecting breast cancer. The issued patent will expire in 2032.

OncoCyt has also obtained an exclusive license from Wistar to certain pending patent applications in the field of molecular diagnostics for lung cancer. The pending claims are directed to compositions of matter and methods useful for detection of lung cancer using specific biomarkers or a panel of specific biomarkers, with projected expiration dates in 2036. Additionally, OncoCyt has obtained from Wistar an exclusive option under which it may license additional issued and pending patents in the field of molecular diagnostics for lung cancer. Patents covered by the exclusive option have issued in the United States and Europe and are pending in the United States, Canada and India. These patents are projected to expire in 2028 - 2030.

Patents Used in Our Plasma Volume Expander Business

We currently hold three issued U. S. patents with methods-of-use claims covering Hextend®. The most recent U.S. patents were issued during May 2011. Our patents in the U.S., which include claims directed to methods-of-use of Hextend®, are expected to remain in force until 2019. Patents covering certain proprietary solutions have also issued in several countries and remain in force in Canada, China, Israel, Japan, New Zealand, and Taiwan.

General Risks Related to Obtaining and Enforcing Patent Protection

There is a risk that any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and be declared invalid or infringing on third party claims. A patent interference proceeding may be instituted with the USPTO 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 on patents and applications filed before March 16, 2013. At the completion of the interference proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex, highly contested legal proceedings, and the 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.

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For patents and applications filed after March 16, 2013 a derivation proceeding may be initiated where the USPTO may determine if one patent was derived from the work of an inventor on another patent. Additionally, there are proceedings at the USPTO (ex parte re-examination, post grant review and an inter partes review proceeding) which allow third parties to challenge the validity of an issued patent where there is a reasonable likelihood of invalidity. As with the USPTO interference proceedings, these proceedings can be expensive to contest and can result in the 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 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.

The enforcement of patent rights often requires litigation against third-party infringers, and such litigation can be costly to pursue. Even if we succeed in having new patents issued or in defending any challenge to issued patents, there is no assurance that our patents will be comprehensive enough to provide us with meaningful patent protection against our competitors.

In addition to relying on patents, we rely on trade secrets, know-how, and continuing technological advancement to maintain our competitive position. We have entered into intellectual property, invention, and non-disclosure agreements with our employees, and it is our practice to enter into confidentiality agreements with our consultants. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of our trade secrets and know-how, or that others may not independently develop similar trade secrets and know-how or obtain access to our trade secrets, know-how, or proprietary technology.

Competition

We face substantial competition in all of fields of business in which we engaged. That competition is likely to intensify as new products and technologies reach the market. Superior new products are likely to sell for higher prices and generate higher profit margins once acceptance by the medical community is achieved. Those companies that are successful at being the first to introduce new products and technologies to the market may gain significant economic advantages over their competitors in the establishment of a customer base and track record for the performance of their products and technologies. Such companies will also benefit from revenues from sales that could be used to strengthen their research and development, production, and marketing resources. All companies engaged in the medical products industry face the risk of obsolescence of their products and technologies as more advanced or cost-effective products and technologies are developed by their competitors. As the industry matures, companies will compete based upon the performance and cost-effectiveness of their products.

Products for Regenerative Medicine

The stem cell industry is characterized by rapidly evolving technology and intense competition. Our competitors include major multinational pharmaceutical companies, specialty biotechnology companies, and chemical and medical products companies operating in the fields of regenerative medicine, cell therapy, tissue engineering, and tissue regeneration. Many of these companies are well established and possess technical, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, certain smaller biotech companies have formed strategic collaborations, partnerships, and other types of joint ventures with larger, well-established industry competitors that afford the smaller companies' potential research and development as well as commercialization advantages. Academic institutions, governmental agencies, and other public and private research organizations are also conducting and financing research activities, which may produce products directly competitive to those we are developing.

We believe that some of our competitors are trying to develop hES cell-, iPS cell-, and hEPC-based technologies and products that may compete with our stem cell products based on efficacy, safety, cost, and intellectual property positions. We are aware that Ocata, which was recently acquired by a subsidiary of Astellas Pharma Inc., is conducting clinical trials of a hES cell product designed to treat age-related macular degeneration. If the Ocata product is proven to be safe and effective, it may reach the market ahead of Cell Cure Neuroscience's OpRege[®].

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We may also face competition from companies that have filed patent applications relating to the propagation and differentiation of stem cells. Those companies include Ocata, which in 2015 had certain US patents issue with claims directed to methods of producing RPE cells and isolating and purifying such cells. We may be required to seek licenses from these competitors in order to commercialize certain products proposed by us, and such licenses may not be granted.

Cancer Diagnostic Testing

The cancer diagnostic test industry is characterized by rapidly evolving technology and intense competition. OncoCyt's competitors include major multinational diagnostic companies and specialty biotechnology companies. Many of these companies are well-established and possess technical, research and development, financial, and sales and marketing resources significantly greater than OncoCyt's. In addition, smaller biotech companies may form strategic collaborations, partnerships, and other types of joint ventures with larger, well established industry competitors that afford these companies' potential research and development and commercialization advantages. Academic institutions, governmental agencies, and other public and private research organizations are also conducting and financing research activities which may produce diagnostic tests directly competitive to those OncoCyt is developing.

Molecular diagnostic competitors in the category of OncoCyt's first planned diagnostic test launch (lung confirmatory) include two currently marketed diagnostic tests. Xpresys Lung was launched in late 2013 by Integrated Diagnostics and that company has recently announced coverage by major payers. The other currently marketed diagnostic test is Early CDT lung, which was launched in 2012 by a European diagnostics company OncImmune Ltd. OncImmune has sold its U.S. assets to a CLIA laboratory, operating under the name OncImmune USA, LLC. Additionally, OncoCyt anticipates competition from Exact Sciences Corp, Gensignia Life Sciences, Inc. and Veracyte, Inc. which have diagnostic tests in the pipeline. Gensignia announced the certification of its CLIA lab in October 2015.

In addition to molecular diagnostics, an imaging competitor has a diagnostic test that may compete directly in confirmatory lung diagnostic testing. VisionGate, Inc. has a sputum test that is read by their proprietary system, which takes an optical CT scan of individual cells to generate 3D images of each cell.

Plasma Volume Expanders

Our plasma volume expander solution, Hextend®, competes with products currently used to treat or prevent hypovolemia, including albumin, other colloid solutions, and crystalloid solutions presently manufactured by established pharmaceutical companies, and with human blood products. To compete with new and existing plasma expanders, we have developed products that contain constituents that may prevent or reduce the physiological imbalances, bleeding, fluid overload, edema, poor oxygenation, and organ failure that can occur when competing products are used.

Hextend® competes with products that are commonly used in surgery and trauma care, and some, especially crystalloids, sell at low prices. The competing products are being manufactured and marketed by established pharmaceutical companies with large research facilities, technical staffs, and financial and marketing resources. B. Braun presently markets Hespan®, an artificial plasma volume expander containing 6% hetastarch in saline solution. Hospira and Teva sell a generic equivalent of Hespan®. Hospira, also markets Voluven®, a plasma volume expander containing a 6% low molecular weight hydroxyethyl starch in saline solution. Sanofi-Aventis, Baxter International, and Alpha Therapeutics sell albumin, and Hospira, Baxter International, and B. Braun sell crystalloid solutions. As a result of the introduction of generic plasma expanders and new proprietary products, competition in the plasma expander market has intensified, and wholesale prices of both hetastarch products and albumin have declined which has forced Hospira and CJ Health to make reduce the price at which they sell Hextend® in order to maintain their

share of the market.

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Government Regulation

Government authorities at the federal, state and local level, and in other countries, extensively regulate among other things, the development, testing, manufacture, quality, approval, distribution, labeling, packaging, storage, record keeping, marketing, import/export and promotion of drugs, biologics, and medical devices. Laboratories performing diagnostic tests such as those being developed by OncoCyte are also subject to regulation at both the federal and state level. Authorities also heavily regulate many of these activities for human cells, tissues and cellular and tissue-based products or HCT/Ps.

FDA and Foreign Regulation of Therapeutic Products

The FDA and foreign regulatory authorities will regulate our proposed products as drugs, biologicals, or medical devices, depending upon such factors as the use to which the product will be put, the chemical composition, and the interaction of the product with the human body. In the United States, the FDA regulates drugs and biologicals under the Federal Food, Drug and Cosmetic Act or FDCA, the Public Health Service Act, or PHSA, and implementing regulations. In addition, establishments that manufacture human cells, tissues, and cellular and tissue-based products are subject to additional registration and listing requirements, including current good tissue practice regulations. Many of Asterias' proposed products will be reviewed by the FDA staff in its Center for Biologics Evaluation and Research ("CBER") Office of Cellular, Tissue and Gene Therapies.

Our domestic human drug and biological products will be subject to rigorous FDA review and approval procedures. After testing in animals to evaluate the potential efficacy and safety of the product candidate, an investigational new drug ("IND") submission must be made to the FDA to obtain authorization for human testing. Extensive clinical testing, which is generally done in three phases, must then be undertaken at a hospital or medical center to demonstrate optimal use, safety, and efficacy of each product in humans. Each clinical study is conducted under the auspices of an independent Institutional Review Board ("IRB"). The IRB will consider, among other things, ethical factors, the safety of human subjects, and the possible liability of the institution.

Clinical trials are generally conducted in three "phases." Phase I clinical trials are conducted in a small number of healthy volunteers or volunteers with the target disease or condition to assess safety. Phase II clinical trials are conducted with groups of patients afflicted with the target disease or condition in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In some cases, an initial trial is conducted in diseased patients to assess both preliminary efficacy and preliminary safety, in which case it is referred to as a Phase I/II trial. Phase III trials are large-scale, multi-center, comparative trials and are conducted with patients afflicted with the target disease or condition in order to provide enough data to demonstrate the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend, or terminate the clinical trial based upon the data which have been accumulated to that point and its assessment of the risk/benefit ratio to the intended patient population. All adverse events must be reported to the FDA. Monitoring of all aspects of the study to minimize risks is a continuing process. The time and expense required to perform this clinical testing can far exceed the time and expense of the research and development initially required to create the product

No action can be taken to market any therapeutic product in the U.S. until an appropriate New Drug Application ("NDA") or Biologics License Application (BLA) has been approved by the FDA. Submission of the application is no guarantee that the FDA will find it complete and accept it for filing. If an application is accepted for filing, following the FDA's review, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. FDA regulations also restrict the export of therapeutic products for clinical use prior to FDA approval. To date, the FDA has not granted marketing approval to any pluripotent stem-based therapeutic products and it is possible that the FDA or foreign regulatory agencies may subject our product candidates to additional or more stringent review than drugs or biologicals derived

from other technologies.

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The FDA offers several programs to expedite development of products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments. A product may be eligible for breakthrough therapy designation if it treats a serious or life-threatening disease or condition and preliminary clinical evidence indicates it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Features of breakthrough therapy designation include intensive guidance from the FDA on an efficient development program, intensive involvement of FDA staff in a proactive, collaborative review process, and rolling review of marketing applications. Under its accelerated approval regulations, the FDA may approve a product based on a surrogate endpoint that is reasonably likely to predict clinical benefits or based on an effect on a clinical endpoint other than survival or irreversible morbidity. The applicant will then be required to conduct additional, post-approval confirmatory trials to verify and describe clinical benefit, and the product may have certain post-marketing restrictions as necessary to assure safe use. The FDA may withdraw approval granted under the traditional route or under an accelerated approval, if it is warranted. The FDA may also consider ways to use the accelerated approval pathway for rare or very rare diseases, and a new review designation has been created to help foster the innovation of promising new therapies with the potential to shorten the timeframe for conducting pivotal trials and speed up patient access to the approved product. There is no assurance that the FDA will grant breakthrough therapy or accelerated approval status to any of our product candidates

Certain Medical Devices

Obtaining regulatory approval of Renevia® or a similar implantable matrix for tissue transplant or stem cell therapy in Europe will require the preparation of a design dossier containing details on the product manufacturing and production methods, analytical controls to assure that the product meets its release specification, data from analytical assay and process validations, ISO 10993 biocompatibility testing, as well as pre-clinical and clinical safety and efficacy data. Completion of the manufacturing, analytical, biocompatibility, and clinical trials represents a majority of the expenses associated with the regulatory application process in Europe. The procedures for obtaining FDA approval to sell products in the U.S. are likely to be more stringent, and the cost greater, than would be the case in an application for approval in Europe.

Combination Products

If we develop any products that are used with medical devices, they may be considered combination products, which are defined by the FDA to include products comprised of two or more regulated components or parts such as a biologic and a device. For example, our HyStem® hydrogel products such as Renevia® may be used to administer one or more pluripotent stem cell-based therapy products. When regulated independently, biologics and devices each have their own regulatory requirements. However, the regulatory requirements for a combination product comprised of a biologic administered with a delivery device can be more complex, because in addition to the individual regulatory requirements for each component, additional combination product regulatory requirements may apply. There is an Office of Combination Products at the FDA that coordinates the review of such products and determines the primary mode of action of a combination product. The definition and regulatory requirements for combination products may differ significantly among other countries in which we may seek approval of our product candidates.

Post-Approval Matters

Even after initial FDA or foreign regulatory agency approval has been obtained, further studies may be required to provide additional data on safety or to gain approval for the use of a product as a treatment for clinical indications other than those initially targeted. Use of a product during testing and after marketing could reveal side effects that could delay, impede, or prevent marketing approval, result in a regulatory agency-ordered product recall, or in regulatory agency-imposed limitations on permissible uses or in withdrawal of approval. For example, if the FDA or foreign regulatory agency becomes aware of new safety information after approval of a product, it may require us to conduct further clinical trials to assess a known or potential serious risk and to assure that the benefit of the product

outweigh the risks. If we are required to conduct such a post-approval study, periodic status reports must be submitted to the FDA or foreign regulatory agency. Failure to conduct such post-approval studies in a timely manner may result in substantial civil or criminal penalties. Data resulting from these clinical trials may result in expansions or restrictions to the labeled indications for which a product has already been approved.

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FDA Regulation of Manufacturing

The FDA regulates the manufacturing process of pharmaceutical products, human tissue and cell products, and medical devices, requiring that they be produced in compliance with cGMP. See “Manufacturing.” The FDA regulates and inspects equipment, facilities, laboratories, processes used in the manufacturing and testing of products prior to providing approval to market products. If after receiving approval from the FDA, a material change is made to manufacturing equipment or to the location or manufacturing process, additional regulatory review may be required. The FDA also conducts regular, periodic visits to re-inspect the equipment, facilities, laboratories and processes of manufacturers following an initial approval. If, as a result of those inspections, the FDA determines that that equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal or administrative sanctions and/or remedies against the manufacturer, including suspension of manufacturing operations. Issues pertaining to manufacturing equipment, facilities or processes may also delay the approval of new products undergoing FDA review.

FDA Regulation of Advertising and Product Promotion

The FDA also regulates the content of advertisements used to market pharmaceutical and biological products. Claims made in advertisements concerning the safety and efficacy of a product, or any advantages of a product over another product, must be supported by clinical data filed as part of an NDA, a BLA, or a pre-market notification or pre-market approval application for a medical device (“PMA”), or an amendment to an NDA, a BLA or a pre-market notification or PMA, and must be consistent with the FDA approved labeling and dosage information for that product.

Foreign Regulation

Sales of pharmaceutical products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. Even if FDA approval has been obtained, approval of a product by comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing the product in those countries. The time required to obtain such approval may be longer or shorter than that required for FDA approval.

Federal Funding of Research

The United States government and its agencies have until recently refused to fund research which involves the use of human embryonic tissue. President Bush issued Executive Orders on August 9, 2001 and June 20, 2007 that permitted federal funding of research on hES cells using only the limited number of hES cell lines that had already been created as of August 9, 2001. On March 9, 2009, President Obama issued an Executive Order rescinding President Bush’s August 9, 2001 and June 20, 2007 Executive Orders. President Obama’s Executive Order also instructed the NIH to review existing guidance on human stem cell research and to issue new guidance on the use of hES cells in federally funded research, consistent with President’s new Executive Order and existing law. The NIH has adopted new guidelines that went into effect July 7, 2009. The central focus of the new 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. Those 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.

In addition to President Obama’s Executive Order, a bipartisan bill has been introduced in the U.S. Senate that would allow Federal funding of hES research. The Senate bill is identical to one that was previously approved by both Houses of Congress but vetoed by President Bush. The Senate Bill provides that hES cells will be eligible for use in research conducted or supported by federal funding if the cells meet each of the following guidelines: (1) the stem cells were derived from human embryos that have been donated from IVF clinics, were created for the purposes of

fertility treatment, and were in excess of the clinical need of the individuals seeking such treatment, (2) prior to the consideration of embryo donation and through consultation with the individuals seeking fertility treatment, it was determined that the embryos would never be implanted in a woman and would otherwise be discarded, and (3) the individuals seeking fertility treatment donated the embryos with written informed consent and without receiving any financial or other inducements to make the donation. The Senate Bill authorizes the NIH to adopt further guidelines consistent with the legislation.

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California State Regulations

The state of California has adopted legislation and regulations that require institutions that conduct stem cell research to notify, and in certain cases obtain approval from, a Stem Cell Research Oversight Committee (“SCRO Committee”) before conducting the research. Advance notice, but not approval by the SCRO Committee, is required in the case of in vitro research that does not derive new stem cell lines. Research that derives new stem cell lines or that involves fertilized human oocytes or blastocysts, or that involves clinical trials or the introduction of stem cells into humans, or that involves introducing stem cells into animals, requires advanced approval by the SCRO Committee. Clinical trials may also entail approvals from IRB at the medical center at which the study is conducted, and animal studies may require approval by an Institutional Animal Care and Use Committee.

All hES cell lines that will be used in our research must be acceptably derived. To be acceptably derived, the pluripotent stem cell line must have either:

- Been listed on the National Institutes of Health Human Embryonic Stem Cell Registry; or
- Been deposited in the United Kingdom Stem Cell Bank; or
- Been derived by, or approved for use by, a licensee of the United Kingdom Human Fertilisation and Embryology Authority; or
- Been derived in accordance with the Canadian Institutes of Health Research Guidelines for Human Stem Cell Research under an application approved by the National Stem Cell Oversight Committee; or
- Been approved by CIRM in accordance with California Code of Regulation Title 17, Section 100081; or
- Been derived under the following conditions:
 - (a) Donors of gametes, embryos, somatic cells, or human tissue gave voluntary and informed consent,
 - (b) Donors of gametes, embryos, somatic cells, or human tissue did not receive valuable consideration. This provision does not prohibit reimbursement for permissible expenses as determined by an IRB,
 - (c) Donation of gametes, embryos, somatic cells, or human tissue was overseen by an IRB (or, in the case of foreign sources, an IRB equivalent), and
 - (d) Individuals who consented to donate stored gametes, embryos, somatic cells, or human tissue were not reimbursed for the cost of storage prior to the decision to donate.

Other hES lines may be deemed acceptably derived if they were derived in accordance with (a), (b), and (d) above and the hES line was derived prior to the publication of the National Academy of Sciences guidelines on April 26, 2005 and a SCRO Committee has determined that the investigator has provided sufficient scientific rationale for the need for use of the line, which should include establishing that the proposed research cannot reasonably be carried out with covered lines that did have IRB approval.

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California regulations also require that certain records be maintained with respect to stem cell research and the materials used, including:

- A registry of all human stem cell research conducted, and the source(s) of funding for this research; and
- A registry of human pluripotent stem cell lines derived or imported, to include, but not necessarily limited to:
 - (a) The methods utilized to characterize and screen the materials for safety;
 - (b) The conditions under which the materials have been maintained and stored;
 - (c) A record of every gamete donation, somatic cell donation, embryo donation, or product of somatic cell nuclear transfer that has been donated, created, or used;
 - (d) A record of each review and approval conducted by the SCRO Committee.

Regulation of Diagnostic Tests

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

As a provider of laboratory testing on human specimens for the purpose of disease diagnosis, prevention, or treatment, OncoCyte will be required to hold certain federal, state and local licenses, certifications and permits to conduct its business. In 1988, Congress enacted CLIA, which established quality standards for all laboratories providing testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. OncoCyte's laboratory will need to obtain a CLIA certificate of accreditation and will be required to meet certain laboratory licensing and other requirements under laws of the states in which it operate or from which OncoCyte receives blood or urine samples for testing.

Under CLIA, a laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health of human beings. Under CLIA OncoCyte will be required to hold a certificate applicable to the complexity of the categories of testing performed and that OncoCyte comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring that they comply with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to be reimbursed for services provided to state and federal health care program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

Under the CLIA, laboratory licensing requires a site inspection, review of standard operating procedures and verification that diagnostic results can be reproduced reliably across a number of different conditions. Before submitting for a license, extensive clinical testing, which is typically done in two phases, must be undertaken at a hospital or medical center to demonstrate optimal use, safety, and efficacy of the test in diagnosing a specific condition. Each clinical study is conducted under the auspices of an IRB that will consider, among other things, ethical factors, the safety of human subjects, and the possible liability of the institution.

Clinical studies are generally conducted in two phases. The first phase is analytical validation which is done in the research laboratory and involves the replication of consistent results for the same sample across a spectrum of different conditions. Once the analytical validation is completed, the assay moves into clinical validation. In clinical validation tests are run to confirm that consistent results for the same sample can be obtained in the actual laboratory

that will conduct the commercial tests.

OncoCytel will be subject to regular surveys and inspections to assess compliance with program standards. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests.

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CLIA and FDA Regulation of Diagnostic Tests

OncoCyte's diagnostic tests will likely be classified as LDTs and consequently be governed under the CLIA regulations, as administered by The Centers for Medicare and Medicaid Services ("CMS"), as well as by applicable state laws. Historically, the FDA has exercised enforcement restraint with respect to most LDTs and has not required laboratories that offer LDTs to comply with FDA requirements for medical devices, such as registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls. In recent years, however, the FDA has stated it intends to end its policy of enforcement restraint and begin regulating certain LDTs as medical devices. On October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement restraint until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance, which may happen in as little as 12 months after the draft guidance is finalized for certain high-priority LDTs. Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA, including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity. We cannot predict the ultimate form or impact of any such FDA guidance and the potential effect on our diagnostic test services.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for OncoCyte's diagnostic tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that proposed legislation discussed above or other new legislation could be enacted into law, or new regulations or guidance could be issued by the FDA. Such new legislation may result in new or increased regulatory requirements for OncoCyte to offer diagnostic tests or services.

If premarket review, including approval, is required, OncoCyte's business could be negatively affected until such review is completed and clearance to market or approval is obtained. If OncoCyte is selling diagnostic tests when new FDA approval requirements are implemented, OncoCyte may be required to suspend sales until premarket clearance or approval is obtained. If OncoCyte's diagnostic tests are allowed to remain on the market but there is uncertainty about the legal status of those tests, if OncoCyte is required by the FDA to label them investigational, or if labeling claims the FDA allows OncoCyte to make are limited, order levels for the use of OncoCyte tests may decline and reimbursement may be adversely affected.

New regulations could also require, among other things, additional clinical studies and submission of a premarket notification or filing a PMA application with the FDA. For example, LDTs with the same intended use as a cleared or approved companion diagnostic are defined in FDA's draft guidance as "high-risk LDTs (Class III medical devices)" for which premarket review would be required. This may include the use of LDTs for screening patients for cancer. See the discussion of FDA regulation of medical devices below under In Vitro Diagnostics. If premarket review is required by the FDA, there can be no assurance that OncoCyte's diagnostic tests will be cleared or approved on a timely basis, if at all, nor can there any be assurance that labeling claims allowed by the FDA will be consistent with OncoCyte's intended claims or will be adequate to support continued adoption of and reimbursement for the tests.

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California State Laboratory Licensing

In addition to federal certification requirements of laboratories under CLIA, licensure will be required and maintained under California law for the San Francisco Bay Area based laboratory that OncoCyte plans to establish. Such laws include standards for the day-to-day operation of a clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, California laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory.

OncoCyte will not be permitted to perform diagnostic tests at the California CLIA laboratory it plans to build, until the laboratory is certified by the state, and if after certification the laboratory falls out of compliance with California standards, the California Department of Health Services (“DHS”) may suspend, restrict or revoke the license to operate the laboratory, assess substantial civil money penalties, or impose specific corrective action plans.

Other States’ Laboratory Licensing

Some states require licensure of out-of-state laboratories that accept specimens from those states. OncoCyte’s laboratory will need to pass various state inspections in order to get licensed to provide LDTs in each of state that requires licensure. In addition to the inspection requirements of the other states, Pennsylvania, Florida and Maryland have laws that require a certificate of compliance, and New York has its own special inspection requirements that must be met, in order to market our diagnostics in those states or to perform diagnostic tests on specimens received from patients residing in those states.

In Vitro Diagnostics

In the future, OncoCyte may elect to develop IVDs, which are regulated by the FDA as medical devices. Medical devices marketed in the United States are subject to the regulatory controls under CLIA, the Federal Food, Drug, and Cosmetic Act, and regulations adopted by the FDA. Some requirements, known as premarket requirements, apply to medical devices before they are marketed, and other requirements, known as post-market requirements, apply to medical devices after they are marketed.

The particular premarket requirements that must be met to market a medical device in the United States will depend on the classification of the device under FDA regulations. Medical devices are categorized into one of three classes, based on the degree of risk they present. Devices that pose the lowest risk are designated as Class I devices, devices that pose moderate risk are designated as Class II devices and are subject to general controls and special controls, and the devices that pose the highest risk are designated as Class III devices and are subject to general controls and premarket approval.

A premarket submission to the FDA will be required for some Class I products, most Class II, and all Class III devices. Most Class I and some Class II devices are exempt from premarket submission requirements. Some Class I and most Class II devices may only be marketed after a 510(k) premarket notification, while a more extensive PMA or Premarket Approval is required to market Class III devices.

Unless and until the FDA’s draft guidance documents are finalized and the resulting new regulatory requirements are phased in our initial confirmatory diagnostics will not require FDA filing before launch. Since the tests are being developed as LDTs, the regulatory pathway that OncoCyte will be following is the CLIA certification and inspection pathway. If the new requirements are phased in or if OncoCyte elects to develop IVDs, those future screenings diagnostics may require a 510(k) submission or a PMA. In a 510(k) submission, the device sponsor must demonstrate that the new device is “substantially equivalent” to a predicate device in terms of intended use, technological characteristics, and performance testing. A 510(k) requires demonstration of substantial equivalence to another device that is legally marketed in the United States. Substantial equivalence means that the new device is at least as safe and

effective as the predicate. A device is substantially equivalent if, in comparison to a predicate it (a) has the same intended use as the predicate; and has the same technological characteristics as the predicate; or (b) has the same intended use as the predicate; and has different technological characteristics and the information submitted to FDA; does not raise new questions of safety and effectiveness; and is demonstrated to be at least as safe and effective as the legally marketed predicate device.

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A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics. A device may not be marketed in the United States until the submitter receives a letter declaring the device substantially equivalent. If the FDA determines that a device is not substantially equivalent, the applicant may resubmit another 510(k) with new data, or request a Class I or II designation through the FDA's de novo process which allows a new device without a valid predicate to be classified into Class I or II if it meets certain criteria, or file a reclassification petition, or submit a PMA.

A new 510(k) submission is required for changes or modifications to an existing approved device, where the modifications could significantly affect the safety or effectiveness of the device or the device is to be marketed for a new or different indication for use.

A PMA for Class III devices is the most stringent type of premarket submission. Before the FDA approves a PMA, the sponsor must provide valid scientific evidence demonstrating reasonable assurance of safety and effectiveness for the device's intended use.

Submission of an application is no guarantee that the CMS or FDA will find it complete and accept it for filing. If an application is accepted for filing or licensing, following the CMS or FDA's review, the CMS or FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval.

Health Insurance Portability and Accountability Act

Under the Health Insurance Portability and Accountability Act ("HIPAA"), the Department of Health and Human Services ("HHS") has issued regulations to protect the privacy and security of protected health information used or disclosed by health care providers, such as us. HIPAA also regulates standardization of data content, codes and formats used in health care transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties.

CMS and the Office of Civil Rights issued a final rule in February 2014 to amend both the HIPAA and CLIA regulations. The final rule amended the HIPAA privacy rule to remove the CLIA laboratory exceptions, and as a result, HIPAA-covered laboratories are now required to provide individuals, upon request, with access to their completed test reports. Under the new rules CLIA laboratories and CLIA-exempt laboratories may provide copies of a patient's completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. These changes to the CLIA regulations and the HIPAA Privacy Rule provide individuals with a greater ability to access their health information, empowering them to take a more active role in managing their health and health care. CLIA laboratories must create and maintain policies, procedures, and other documentation necessary to inform patients of the right to access laboratory test reports and how to exercise that right.

The requirements under these regulations may periodically change and could have an effect on OncoCyte's business operations if compliance becomes substantially more costly than under current requirements. New laws governing privacy may also be adopted in the future. We can provide no assurance that OncoCyte will remain in compliance with diverse privacy requirements in all of the jurisdictions in which it does business. Failure to comply with privacy requirements could result in civil or criminal penalties, which could have a materially adverse effect on OncoCyte's business.

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Physician Referral Prohibitions

Under a federal law directed at “self-referral,” commonly known as the Stark Law, there are prohibitions, with certain exceptions, on Medicare and Medicaid payments for laboratory tests referred by physicians who personally, or through a family member, have a “financial relationship”—including an investment or ownership interest or a compensation arrangement—with the clinical laboratory performing the tests. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) certain space and equipment rental arrangements that satisfy certain requirements, and (4) personal services arrangements that satisfy certain requirements. The laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law, and Medicaid reimbursements may be at risk as well. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from the federal health care programs. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

Corporate Practice of Medicine

A number of states, including California, do not allow business corporations to employ physicians to provide professional services. This prohibition against the “corporate practice of medicine” is aimed at preventing corporations such as OncoCytte from exercising control over the medical judgments or decisions of physicians. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. If regulatory authorities or other parties in any jurisdiction successfully assert that OncoCytte is engaged in the unauthorized corporate practice of medicine, OncoCytte could be required to restructure its contractual and other arrangements. In addition, violation of these laws may result in sanctions imposed against OncoCytte and/or the professional through licensure proceedings, and OncoCytte could be subject to civil and criminal penalties that could result in exclusion from state and federal health care programs.

Federal and State Fraud and Abuse Laws

A variety of federal and state laws prohibit fraud and abuse. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General for HHS, and various state agencies. In addition, the Medicare and Medicaid programs increasingly use a variety of contractors to review claims data and to identify improper payments as well as fraud and abuse. These contractors include Recovery Audit Contractors, Medicaid Integrity Contractors and Zone Program Integrity Contractors. In addition, CMS conducts Comprehensive Error Rate Testing audits, the purpose of which is to detect improper Medicare payments. Any overpayments identified must be repaid unless a favorable decision is obtained on appeal. In some cases, these overpayments can be used as the basis for an extrapolation, by which the error rate is applied to a larger universe of claims, and which can result in even higher repayments.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, to induce or in return for either the referral of an individual, or the furnishing, recommending, or arranging for the purchase, lease or order of any health care item or service reimbursable, in whole or in part, under a federal health care program. The definition of “remuneration” has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, ownership interests and providing anything at less than its fair market value. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the health care industry, the Office of Inspector General for HHS has issued a series of regulatory “safe harbors.” These safe harbor regulations set forth certain requirements that, if met, will assure immunity from prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal

Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued.

HIPAA also created new federal crimes, including health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs, such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs.

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Many states have laws similar to the federal laws described above and the state laws may be broader in scope and may apply regardless of payor.

Medicare, Medicaid, and Similar Reimbursement Programs

Sales of the therapeutic products and diagnostic tests that we and our subsidiaries plan to offer will depend, in part, on the extent to which the costs of those products or tests will be covered by third-party payors, such as government health programs, commercial insurance, and managed healthcare organizations.

The containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. In the United States, the federal and many state governments have adopted or proposed initiatives relating to Medicaid and other health programs that may limit reimbursement or increase rebates that providers are required to pay to the state. Medicare for example, currently requires a 2% reduction to Medicare payment rates to providers due to federal budget cuts referred to as “sequestration”. In addition to government regulation, managed care organizations in the United States, which include medical insurance companies, medical plan administrators, health-maintenance organizations, hospital and physician alliances and pharmacy benefit managers, continue to put pressure on the price and usage of healthcare products. Managed care organizations seek to contain healthcare expenditures, and their purchasing strength has been increasing due to their consolidation into fewer, larger organizations and a growing number of enrolled patients. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If third-party payors do not consider our products to be cost-effective compared to other therapies or diagnostic tests, they may not cover our products or diagnostic tests as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Therapeutic Products: Third- Party Reimbursement

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, “ACA”) is accelerating changes in the U.S. healthcare marketplace, and the potential for additional pricing and access pressures continues to be significant. ACA already increased many of the mandatory discounts and rebates and imposed a new Branded Prescription Pharmaceutical Manufacturers and Importers fee payable each year by manufacturers of therapeutic products. Many of ACA developments may impact drug utilization, in particular branded drug utilization. Some employers, seeking to avoid the tax on high-cost health insurance in the ACA to be imposed in 2018, are already scaling back healthcare benefits. Some health plans and pharmacy benefit managers are seeking greater pricing predictability from pharmaceutical manufacturers in contractual negotiations. Other health plans and pharmacy benefit managers are increasing their focus on spending on specialty medications by implementing co-insurance in place of a flat co-payment. Because co-insurance passes on a percentage of the cost of a drug to the patient, this shift has the potential to significantly increase patient out-of-pocket costs.

Many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred so we cannot predict the impact of ACA on our business or the business of our subsidiaries. Furthermore, although the United States Supreme Court upheld the constitutionality of most of the ACA, some states have indicated that they intend to not implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal parts of the ACA. While ACA’s ultimate goal is to expand health insurance coverage and increase access to medical care generally, the long-term impact of the ACA on our business and the demand for our products remains uncertain.

The increasing pressure on U.S. providers to deliver healthcare at a lower cost and to ensure that those expenditures deliver demonstrated value in terms of health outcomes has led to policy efforts designed specifically to reduce patient

out-of-pocket costs. A number of the candidates for the 2016 U.S. presidential elections have already introduced various policy proposals. Examples of proposals that have been discussed and debated but not yet enacted include state ballot initiatives designed to require pharmaceutical manufacturers to publicly report proprietary pricing information or state legislative efforts to place a maximum price ceiling, or cap, on pharmaceutical products purchased by state agencies. The looming political changes and continuing policy efforts will have a significant impact on our industry and our future.

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CMS recently proposed a new plan to alter Medicare Part B, which pays for medicines administered in doctors' offices 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.

We face similar issues outside of the United States. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

Diagnostic Tests: Third-Party Billing, Coverage, and Reimbursement

OncoCytte will face additional third-party reimbursement challenges for the diagnostic tests that it plans to provide. Revenues from OncoCytte's clinical laboratory testing will be derived from several different sources. Depending on the billing arrangement, the instruction of the ordering physician and applicable law, parties that may reimburse OncoCytte for its services include:

- Third-party payers that provide coverage to the patient, such as an insurance company, a managed care organization or a governmental payer program;

- Physicians or other authorized parties, such as hospitals or independent laboratories, that order the testing service or otherwise refer the testing services to OncoCytte; or

- Patients in cases where the patient has no insurance, has insurance that partially covers the testing, or owes a co-payment, co-insurance or deductible amount.

Medicare

We expect that a substantial portion of the patients for whom OncoCytte may perform diagnostic tests will have Medicare as their primary medical insurance. We cannot assure that, without Medicare reimbursement OncoCytte's planned tests will produce sufficient revenues to enable OncoCytte to reach profitability and achieve its other commercial objectives.

Clinical diagnostic laboratory tests are generally reimbursed under the Medicare Clinical Laboratory Fee Schedule. Reimbursement under the Medicare program for the diagnostic tests that OncoCytte will offer is based on the Medicare

Clinical Laboratory Fee Schedule, which is subject to geographic adjustments and is updated annually.

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Medicare payment amounts are established for each Current Procedural Terminology (“CPT”) code. CPT codes are the main data code set used by physicians, hospitals, laboratories and other health care professionals to report separately-payable clinical laboratory services for reimbursement purposes. The CPT coding system is maintained and updated on an annual basis by the American Medical Association (“AMA”). Each year, new laboratory test codes are added to the fee schedules and corresponding fees are developed in response to a public comment process. OncoCyte will request a unique CPT code from the AMA for its diagnostic test. Any updates and changes in CPT coding and reimbursement methods may impact OncoCyte’s revenues. The introduction of new codes by CMS in combination with other actions with regard to pricing could result in lower reimbursements to OncoCyte than those we may anticipate, or could result in a reduction in the payments that OncoCyte may receive, for OncoCyte’s tests and could make it more difficult to obtain coverage from Medicare or other payers. There can be no guarantees that Medicare and other payers will establish positive or adequate coverage policies or reimbursement rates.

In addition, under the Clinical Laboratory Fee Schedule, Medicare also sets a cap on the amount that it will pay for any individual test. This cap, usually referred to as the National Limitation Amount, is set at a percentage of the median of all the contractor fee schedule amounts for each billing code.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither OncoCyte nor any other party, such as a reference laboratory, may receive reimbursement from Medicare for the service.

Legislative and Regulatory Changes Impacting Medicare Reimbursements

From time to time, Congress has revised the Medicare statute and the formulas it establishes for the Medicare Clinical Laboratory Fee Schedule. The payment amounts under the Medicare fee schedules are important because they not only will determine OncoCyte’s reimbursement under Medicare, but those payment amounts are also often used as a basis for payment amounts set by other governmental and private third-party payers. For example, state Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for clinical laboratory services furnished to Medicaid recipients.

Under the statutory formula for Medicare Clinical Laboratory Fee Schedule amounts, increases are made annually based on the Consumer Price Index for All Urban Consumers as of June 30 for the previous twelve-month period. The ACA has, among other things, imposed cuts to the Medicare reimbursement for clinical laboratories. The ACA replaced the 0.5% cut enacted by the Medicare Improvements for Patients and Providers Act with a “productivity adjustment” that will reduce the Consumer Price Index update in payments for clinical laboratory tests. The ACA includes a 1.75% reduction in the CPI update for clinical laboratories for the years 2011 through 2015. The Middle Class Tax Relief and Job Creation Act of 2012 (“MCTRJCA”), enacted in 2012, mandated an additional change in reimbursement for clinical laboratory service programs. This legislation required CMS to reduce the Medicare Clinical Laboratory Fee Schedule by 2% in 2013, which in turn has served as a base for subsequent years. As a consequence of the changes required by ACA and MCTRJCA, payment for clinical laboratory services has gone down in recent years.

Under the Protecting Access to Medicare Act of 2014 (“PAMA”), which was signed to law in April 2014, there will be major changes to the payment formula under the Medicare Clinical Laboratory Fee Schedule. As of January 1, 2016, each clinical laboratory must report laboratory test payment data for each Medicare-covered clinical diagnostic laboratory test that it furnishes during a time period to be defined by future regulations. The reported data must include the payment rate reflecting all discounts, rebates, coupons and other price concessions and the volume of each test that was paid by each private payer, such as health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations.

PAMA has the potential to significantly impact the way that laboratory tests are reimbursed by Medicare. Reimbursement rates for advanced diagnostic tests will initially be based on list prices or charges and then will be pegged to the average price paid by commercial third party payers such as health insurance companies. Diagnostics in this category must meet one of the following criteria:

- Analysis of multiple biomarkers of DNA, RNA or proteins combined with a unique algorithm to yield a single patient-specific result;
- Cleared or approved by the FDA; or
- Meets other similar criteria established by the Secretary of Health and Human Services.

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Beginning January 1, 2017, Medicare payment for any new advanced diagnostic test will be based on the list price/charge. After the test is commercially available for two quarters, the laboratory will be required to report payment and volume information and this 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, generally 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.

Congress has proposed on several occasions to impose a 20% coinsurance charge on patients for clinical laboratory tests reimbursed under the Medicare Clinical Laboratory Fee Schedule, which would require OncoCyte to bill patients for these amounts. Because of the relatively low reimbursement for many clinical laboratory tests, in the event that Congress were to ever enact such legislation, the cost of billing and collecting for these services would often exceed the amount actually received from the patient and effectively increase OncoCyte's costs of billing and collecting.

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. 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 its determinations for future diagnostics.

Some Medicare claims may be subject to policies issued by the Medicare Administrative Contractor ("MAC") for California. CMS relies on a network of MACs to process Medicare claims, and MACs serve as the primary operational contact between the Medicare Fee-For-Service program, and approximately 1.5 million health care providers enrolled in the program. Palmetto GBA, acting on behalf of many MACs, issued a Local Coverage Determination that affects coverage, coding and billing of many molecular diagnostic tests. Under this Local Coverage Determination, Palmetto GBA stated that it would not cover any molecular diagnostic tests unless the test is expressly included in a National Coverage Determination issued by CMS or a Local Coverage Determination or coverage article issued by Palmetto GBA. Denial of coverage for OncoCyte's diagnostic tests by Palmetto GBA or its successor MAC, Noridian Healthcare Solutions, or reimbursement at inadequate levels, would have a material adverse impact on OncoCyte's business and on market acceptance of OncoCyte's planned diagnostic tests.

Private and Governmental Third Party Payers

Where there is a private or governmental third-party payer coverage policy in place, OncoCyte will bill the payer and the patient in accordance with the established policy. Where there is no coverage policy in place, OncoCyte will pursue reimbursement on a case-by-case basis. OncoCyte's efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claims denials, could take a substantial amount of time, and bills may not be paid for many months, if at all. Furthermore, if a third-party payer denies coverage after final appeal, OncoCyte may not receive payment at all.

Reimbursement rates paid by private third-party payers can vary based on whether the provider is considered to be an "in-network" provider, a participating provider, a covered provider, an "out-of-network" provider or a non-participating provider. These definitions can vary among payers. An in-network provider usually has a contract with the payor or benefits provider. This contract governs, among other things, service-level agreements and reimbursement rates. In certain instances an insurance company may negotiate an in-network rate for OncoCyte's testing. An in-network provider may have rates that are lower per test than those that are out-of-network, and that rate can vary widely. Rates vary based on the payor, the testing type and often the specifics of the patient's insurance plan. If a laboratory agrees to

contract as an in-network provider, it generally expects to receive quicker payment and access to additional covered patients. However, it is likely that OncoCyte will initially be considered an “out-of-network” or non-participating provider by payers who cover the vast majority of patients until such time that OncoCyte can negotiate contracts with these payers.

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We cannot predict whether, or under what circumstances, payers will reimburse for all components of OncoCyte's tests. Full or partial denial of coverage by payers, or reimbursement at inadequate levels, would have a material adverse impact on OncoCyte's business and on market acceptance of OncoCyte's diagnostic tests.

Direct Billing Laws and Other State Law Restrictions on Billing for Laboratory Services

Laws and regulations in certain states prohibit laboratories from billing physicians or other purchasers for testing that they order. Some states may allow laboratories to bill physicians directly but may prohibit the physician and, in some cases, other purchasers from charging more than the purchase price for the services, or may allow only for the recovery of acquisition costs, or may require disclosure of certain information on the invoice. In some cases, and if not prohibited by law or regulation, OncoCyte may bill physicians, hospitals and other laboratories directly for the services that they order. An increase in the number of states that impose similar restrictions could adversely affect OncoCyte by encouraging physicians to perform laboratory services in-house or by causing physicians to refer services to other laboratories that are not subject to the same restrictions.

Employees

As of December 31, 2015, we employed one hundred thirty-three employees. Thirty nine are BioTime employees and ninety-four are employees of our subsidiaries. One hundred and twenty-six persons are on a full-time basis and seven persons on a part-time basis. Forty-one full-time employees and three part-time employees hold Ph.D. degrees in one or more fields of science. None of our employees are covered by a collective bargaining agreement.

Item 1A. Risk Factors

Our business is subject to various risks, including those described below. You should consider the following risk factors, together with all of the other information included in this report, which could materially adversely affect our proposed operations, our business prospects, and financial condition, and the value of an investment in our business. There may be other factors that are not mentioned here or of which we are not presently aware that could also affect our business operations and prospects.

Risks Related to Our Business Operations

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

Our total comprehensive losses for the fiscal years ended December 31, 2015, 2014, and 2013 were \$47.8 million, \$36.4 million, and \$43.8 million respectively, and we had an accumulated deficit of \$229.2 million, \$182.2 million, and \$145.8 million, as of December 31, 2015, 2014, and 2013, respectively. We primarily finance our operations through the sale of equity securities, licensing fees, royalties on product sales by our licensees, research grants, and 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 products, diagnostic tests, and technology.

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

· We are attempting to develop new medical products and technologies.

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

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The experimentation we are doing is costly, time consuming, and uncertain as to its results. We incurred research and development expenses amounting to \$42.6 million, \$37.5 million, and \$26.6 million during the fiscal years ended December 31, 2015, 2014, and 2013, respectively, excluding \$17.5 million charged as in process research and development expenses during 2013 in accordance with ASC 805-50 on account of Asterias' acquisition of certain assets from Geron.

If we are successful in developing a new technology or product, refinement of the new technology or product and definition of the practical applications and limitations of the technology or product may take years and require the expenditure of large sums of money. Future clinical trials of new therapeutic products, particularly those products that are regulated as drugs or biological, will be very expensive and will take years to complete. We may not have the financial resources to fund clinical trials on our own and we may have to enter into licensing or collaborative arrangements with larger, well-capitalized pharmaceutical companies in order to bear the cost. Any such arrangements may be dilutive to our ownership or economic interest in the products we develop, and we might have to accept a royalty payment on the sale of the product rather than receiving the gross revenues from product sales.

The operations of Asterias and OncoCyte will result in an increase in our operating expenses and losses on a consolidated basis

The expansion of the operations of our subsidiaries Asterias and OncoCyte will involve substantial expense, including but not limited to hiring additional research and management personnel, and, in the case of OncoCyte, 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.

Asterias and OncoCyte are a public companies and will incur costs associated with audits of their respective 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 BioTime for similar purposes.

As a developer of therapeutic products derived from pluripotent stem, Asterias will face substantially the same kind of risks that affect our business, as well as the risks related to our industry generally.

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

The USPTO issued certain RPE-related patents to Ocata in 2015, with claims directed to methods of producing RPE cell compositions for human therapy. If the process used by Cell Cure Neurosciences to manufacture RPE cells for OpRegen® 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 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's business of selling products for use in stem cell research depends on the growth of stem cell research, without which there may be no market or only a very small market for our products and technology. The likelihood that stem cell research will grow depends upon the successful development of stem cell products that can be used to treat disease or injuries in people or that can be used to facilitate the development of other 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 have future INDs cleared by the FDA.

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There can be no assurance that any safe and efficacious human medical applications will 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.

We are providing funding for the development of new software products

Our subsidiary LifeMap Sciences has formed a new subsidiary, LifeMap Solutions, Inc., 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 there is no certainty that LifeMap Solutions will be successful in developing its planned new products or that it will be successful 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.

Sales of our products to date have not been sufficient to generate an amount of revenue sufficient to cover our operating expenses

The revenues that we have received from sales of products have not been sufficient to pay our operating expenses. This means that we and our subsidiaries need to successfully develop and market or license additional products and earn additional revenues in sufficient amounts to meet our operating expenses.

Sales of the products we may develop will be adversely impacted by the availability of competing products

Sales of Hextend® have already been adversely impacted by the availability of other products that are commonly used in surgery and trauma care and sell at low prices.

Ocata, which was recently acquired by a subsidiary of Astellas Pharma, Inc. for \$379 million, is conducting clinical trials of a pluripotent stem cell product designed to treat AMD. If the Ocata product is proven to be safe and effective, it may reach the market ahead of OpRegen®. Moreover, Ocata was recently issued a patent pertaining to the manufacture of RPE products that could adversely impact the rights of Cell Cure Neurosciences to manufacture OpRegen®.

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

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

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Competing products are being manufactured and marketed by established pharmaceutical companies. For example, B. Braun presently markets Hespan®, an artificial plasma volume expander, and Hospira, Inc. and Teva Pharmaceutical Industries, Inc. sell a generic equivalent of Hespan®. Hospira also markets Voluven®, a plasma volume expander containing a 6% low molecular weight hydroxyethyl starch in saline solution.

Competing products for the diagnosis and treatment of cancer are being manufactured and marketed by established pharmaceutical companies, and more cancer diagnostics and therapeutics are being developed by those companies and by other smaller biotechnology companies. Other companies, both large and small, 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.

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.

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®.

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, largely through our subsidiaries, and we and our subsidiaries will need to raise additional capital to pay operating expenses until we are able to generate sufficient revenues from product sales, royalties, and license fees.

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

Our ability, and the ability of our subsidiaries, to raise additional equity or debt capital will depend not only on progress made in developing new products and technologies, but also will depend on access to capital and conditions in the capital markets. There is no assurance that we and our subsidiaries, even those that have shares listed on the NYSE MKT, will 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 by us or our subsidiaries could result in the dilution of the interests of present shareholders.

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

At December 31, 2015, we had \$42.2 million of cash and cash equivalents on hand, of which \$22.1 million was held by our subsidiaries. There can be no assurance that we or our subsidiaries will be able to raise additional funds on favorable terms or at all, or that any funds raised will be sufficient to permit us or our subsidiaries to develop and market our products and technology. Unless we and our subsidiaries are able to generate sufficient revenue or raise additional funds when needed, it is likely that we will be unable to continue our planned activities, even if we make progress in our research and development projects.

We 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.

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.

We and our subsidiaries 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 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 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 may incur, depending upon the nature and extent of any provable injuries, could exceed any insurance coverage that we or our subsidiaries 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

BioTime stem cell research programs, and to a lesser extent, the programs of BioTime's subsidiaries, are directed primarily by our Co-Chief Executive Officers, Dr. Michael West and Adi Mohanty. BioTime's subsidiaries are

directed by their respective management teams. The loss of the services of Dr. West, Mr. Mohanty or other members of senior management of BioTime or of our subsidiaries could have a material adverse effect on us.

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

If appropriate opportunities become available, we might 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.

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 U.S. 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 BioTime itself 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 BioTime 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.

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

The operation of our business through multiple subsidiaries, two of which are public companies, will result in certain administrative expense that we would not incur if all of our operations were conducted within BioTime itself. Our subsidiaries generally provide compensation to their own executive management teams and members of their boards of directors who are not employees of BioTime or a BioTime subsidiary. 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 BioTime and the subsidiaries, and from the obligations of Asterias and OncoCyte to prepare and file their own periodic financial and informational reports and proxy materials with the SEC and to hold annual meetings of their shareholders.

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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 BioTime and the 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.

Risks Related to Our Industry

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

If we do not receive regulatory approvals we will not be permitted to sell our 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 cannot be presently determined, but could exceed our current 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.

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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 (IRB) 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;
- 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 (NIH) has adopted new guidelines for determining the eligibility of hES cell lines for use in federally funded research. The central focus of the proposed guidelines is to assure that hES cells used in federally funded research were derived from human embryos that were created for reproductive purposes, were no longer needed for this purpose, and were

voluntarily donated for research purposes with the informed written consent of the donors. The hES cells that were derived from embryos created for research purposes rather than reproductive purposes, and other hES cells that were not derived in compliance with the guidelines, are not eligible for use in federally funded research.

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

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

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

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

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

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

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.

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

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

In Europe, 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 parthenogenetically 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.

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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 United States Patent and Trademark Office (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 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

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.

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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 implementation of the 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 and to 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.

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The ACA also introduced a biosimilar pathway that will permit companies to obtain FDA approval of generic versions of existing biologics based upon reduced documentation and data requirements deemed sufficient to demonstrate safety and efficacy than are required for the pioneer biologics. 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, including a possible increase in patent challenges. The FDA has reported meeting with sponsors who are interested in developing biosimilar products, and is developing regulations to implement 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' offices 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.

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Risks Related to our Dependence on Third Parties

Asterias could lose its CIRM grant 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.

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.

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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. There can be no assurance we will 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 through which Asterias acquired Geron's stem cell assets (the "Asset Contribution Agreement"), 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 BioTime 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 the BioTime 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 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.

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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 LDTs that will be performed at a diagnostic laboratory that OncoCyte plans to operate. The decision to develop and commercialize LDTs will give rise to certain risks related to the operation of the business of operating a diagnostic laboratory and performing LDTs, including the following risks.

OncoCyte will need to obtain regulatory approval of its diagnostic laboratory facilities

OncoCyte will need to receive certification for its planned diagnostic laboratory under the CLIA. In addition to meeting federal regulatory requirements, each state has its own laboratory certification and inspection requirements for a CLIA laboratory that must be met in order to sell diagnostic tests in the state. CLIA licensed laboratories can lose their licenses if problems arise during periodic regulatory inspections.

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

The FDA issued two draft guidance documents that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs such as those OncoCyte is developing. If 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 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.

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.

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

The ACA substantially changed the way health care is financed by both governmental and private insurers. Among the ACA's key changes, 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 OncoCyt's diagnostic tests.

The Protecting Access to Medicare Act of 2014 ("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 OncoCyt to bill patients for these amounts. In the event that Congress were to ever enact such legislation, the cost of billing and collecting for OncoCyt'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.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect OncoCyt. 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 OncoCyt's business, financial condition, results of operations and cash flows.

Because of certain Medicare billing policies, OncoCyt 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 ("MACs"). Reimbursement for diagnostic testing may be

negatively impacted by California MAC policies.

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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 Shares

Ownership of our common shares will entail certain risks associated with the volatility of prices for our common shares and the fact that we do not pay dividends on our common shares.

Because we are engaged in the development of pharmaceutical and stem cell therapy products and cancer diagnostic tests, the price of our common shares may rise and fall rapidly

The market price of our common shares, like that of the shares of many biotechnology companies, has been highly volatile.

The price of our common shares 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, prices of our common shares 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 result in a significant rapid decline in the market price of our common shares.

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

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 common shares.

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

We do not pay cash dividends on our common shares. 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 common shares. This means that our common shares 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 common shares and this may have a negative impact on the market price of our common shares

The trading market for our common shares will depend, in part, on the research and reports that securities analysts publish about our business and our common shares. We do not have any control over these analysts. There is no guarantee that securities analysts will cover our common shares. If securities analysts do not cover our common shares, the lack of research coverage may adversely affect the market price of those shares. If securities analysts do cover our common shares, they could issue reports or recommendations that are unfavorable to the price of our common shares, 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 common shares 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 common shares may experience dilution of their ownership interests because of the future issuance of additional common shares and preferred shares by us and our subsidiaries

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 127,000,000 shares of capital stock consisting of 125,000,000 common shares and 2,000,000 “blank check” preferred shares. As of December 31, 2015, there were 94,894,140 common shares outstanding of which 4,472,586 were held by our subsidiaries, 5,194,313 common shares reserved for issuance upon the exercise of outstanding options under our employee stock option plans; and 9,190,782 shares reserved for issuance upon the exercise of common share purchase warrants, including the publicly traded warrants.

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. 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 the subsidiaries, with a resulting dilutive effect on the ownership interest of our shareholders in our consolidated enterprise.

We and our subsidiaries may issue additional common shares or other securities that are convertible into or exercisable for common shares 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 common shares or other securities may create downward pressure on the trading price of our common shares.

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

ownership of the subsidiaries.

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

The operation of some of our subsidiaries has been financed in part through the sale of capital stock in those subsidiaries, and our subsidiaries may sell shares of their capital stock in the future for financing purposes. The prices at which our subsidiaries 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 common shares trade in the market. A sale of capital stock of one of our subsidiaries at a price that the market perceives as low could adversely impact the market price of our common shares. Even if our subsidiaries sell their capital stock at prices that reflect arm's length negotiation with investors, there is no assurance that those prices will reflect a true fair market value or that the ascribed value of the subsidiaries based on those share prices will be fully reflected in the market value of our common shares.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

BioTime Facilities

Our principal offices and laboratory facilities comprise 30,795 square feet of rentable space in two buildings located in an office park setting at 1010 and 1020 Atlantic Avenue, in Alameda, California. OrthoCyte and OncoCyte share this space with us and it is where OncoCyte plans to establish its CLIA lab.

Base rent during the initial seven year term of the Lease for the new office and research space will be as shown in the following table:

	Annual	Monthly
	Base	Installment
<u>Lease Year</u>	Rent	of Base Rent
1	\$776,034	\$ 64,669
2	\$798,206	\$ 66,517
3	\$824,074	\$ 68,672
4	\$846,246	\$ 70,520
5	\$872,114	\$ 72,676
6	\$897,982	\$ 74,831
7	\$927,545	\$ 77,295

In addition to base rent, we will pay a pro rata portion of increases in certain expenses, including real property taxes, utilities (to the extent not separately metered to our leased space) and the landlord's operating expenses, over the amounts of those expenses incurred by the landlord during 2016.

We also lease an office and research facility located in San Diego, California that is used for the development of new differentiation and cellular reprogramming research products for Ascendance. The lease covers approximately 1,267 square feet of space. The lease term will end on July 31, 2016. BioTime will pay base rent of \$2,787 per month, plus operational costs of maintaining the leased premises.

We also currently pay \$5,050 per month for the use of approximately 900 square feet of office space in New York City, which is made available to us by one of our directors at his cost for use in conducting meetings and other business affairs.

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Asterias Facilities

Asterias leases an office and research facility in a building with approximately 44,000 square feet of space located in Fremont, California. Asterias uses the facility primarily to produce human embryonic stem cells and related products under cGMP.

The lease is for a term of 96 months, commencing on October 1, 2014, with two available five-year options to extend the term. Base rent is presently \$105,142 per month and will increase by approximately 3% annually on every October 1 during the remainder of the lease term.

In addition to monthly base rent, Asterias will pay all real estate taxes, insurance and the cost of maintenance, repair and replacement of the leased premises.

Asterias also currently pays \$4,000 per month for the use of approximately 120 square feet of the office space in New York City that is used to conduct meetings and other business affairs. The lease originally for one year commencing July 1, 2014 was extended through June 30, 2016.

Cell Cure Neurosciences Facilities

Cell Cure Neurosciences leases approximately 1,075 square meters of office and laboratory space in Hadassah Ein Kerem, in Jerusalem, Israel under a lease that expires on November 30, 2016. Base monthly rent for that facility is approximately ILS 21,930 (approximately US\$5,600). In addition to base rent, Cell Cure Neurosciences pays a pro rata share of real property taxes and certain costs related to the operation and maintenance of the building in which the leased premises are located. As of December 31, 2015 Cell Cure Neurosciences has a liability of ILS 163,000 (approximately US\$42,000) in improvement costs. Cell Cure Neurosciences also leases in the same premises an additional 725 square meters of cGMP clean room, laboratories, warehousing and office space under a lease that expires in December 2020. The lease payment is ILS 28,275 (approximately US\$7,160).

LifeMap Facilities

LifeMap Sciences leases approximately 104 square meters of office space in Tel Aviv, Israel under a lease expiring on June 19, 2016. Base monthly rent under the lease is ILS 7,280 (approximately US\$1,800) per month. In addition to base rent, LifeMap Sciences pays a pro rata share of real property taxes and certain costs related to the operation and maintenance of the building in which the leased premises are located. LifeMap Sciences also leases several parking spots.

LifeMap Sciences leases approximately 120 square meters of office space in Hong Kong under a lease that commenced on December 1, 2015 and expires on May 31, 2016. Base monthly rent under the lease is HK\$12,500 (approximately US \$1,500) per month. In addition to base rent, LifeMap pays certain costs related to the operation of the building in which the leased premises are located.

LifeMap Sciences leases approximately 750 square feet of office space in Marshfield, Massachusetts under a lease that expires on September 30, 2018. Base monthly rent under the lease is \$1,216 per month.

LifeMap Sciences also leases approximately 200 square feet of office space in Hoboken, New Jersey under a lease that expires on February 28, 2018. The lease is cancelable at any time prior to expiration date with a 60 days' advanced notice in writing. Base monthly rent under the lease is \$1,150 per month.

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LifeMap Solutions leases approximately 386 square feet of office space in San Jose, California under a lease that expires on May 31, 2016. Base monthly rent under the lease is \$5,457 per month.

Item 3. Legal Proceedings

From time to time, we and our subsidiaries may be involved in routine litigation incidental to the conduct of our business. We are not presently a party to any pending litigation.

Item 4. Mine Safety Disclosures

Not applicable

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Our common shares are traded on the NYSE MKT and on the TASE under the ticker symbol BTX. The following table sets forth the range of high and low closing prices for our common shares for the fiscal years ended December 31, 2014 and 2015 as reported by the NYSE MKT:

Quarter Ended	High	Low
March 31, 2014	\$4.13	\$3.11
June 30, 2014	\$3.29	\$2.29
September 30, 2014	\$3.79	\$2.35
December 31, 2014	\$3.78	\$2.95
March 31, 2015	\$5.46	\$3.81
June 30, 2015	\$5.88	\$3.51
September 30, 2015	\$3.71	\$2.53
December 31, 2015	\$4.38	\$3.19

As of February 29, 2016, there were 14,515 holders of the common shares based on the share position listing.

The following table shows certain information concerning the options outstanding and available for issuance under all of our compensation plans and agreements as of December 31, 2015 (in thousands, except weighted average exercise prices):

Plan Category	Number of Shares to be Issued upon Exercise of Outstanding Options, Warrants, and Rights	Weighted Average Exercise Price of the Outstanding Options, Warrants, and Rights	Number of Shares Remaining Available for Future Issuance under Equity Compensation Plans
BioTime Equity Compensation Plans Approved by Shareholders	5,194	\$ 3.93	5,257

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The following table shows certain information concerning the options outstanding and available for issuance under all of the compensation plans and agreements for our subsidiary companies as of December 31, 2015 (in thousands):

	Number of Shares to be Issued upon Exercise of Outstanding Options, Warrants, and Rights	Weighted Average Exercise Price of the Outstanding Options, Warrants, and Rights	Number of Shares Remaining Available for Future Issuance under Equity Compensation Plans
Asterias Equity Compensation Plans Approved by Shareholders ⁽¹⁾⁽²⁾	5,178	\$ 3.2	2,067
OrthoCye Equity Compensation Plans Approved by Shareholders ⁽¹⁾	2,629	\$ 0.08	1,371
OncoCye Equity Compensation Plans Approved by Shareholders ⁽¹⁾	2,240	\$ 2.03	1,757
ReCye Therapeutics Equity Compensation Plans Approved by Shareholders ⁽¹⁾	1,279	\$ 2.05	2,721
BioTime Asia Equity Compensation Plans Approved by Shareholders ⁽¹⁾	1	\$ 0.01	1
Cell Cure Neurosciences Compensation Plans Approved by Shareholders ⁽¹⁾	24	\$ 27.89	2
LifeMap Sciences Equity Compensation Plans Approved by Shareholders ⁽¹⁾	1,795	\$ 1.47	547
LifeMap Solutions Compensation Plans Approved by Shareholders ⁽¹⁾	14	\$ 500	5

(1) BioTime is, directly or through one or more subsidiaries, the majority shareholder.

(2) Includes 200,000 shares of restricted stock granted.

Additional information concerning our 2012 Equity Incentive Plan and the stock option plans of our subsidiaries may be found in Note 10 to the Consolidated Financial Statements.

Dividend Policy

We have never paid cash dividends on common shares 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 shares 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 ContentPerformance Measurement Comparison⁽¹⁾

The following graph compares total stockholder returns of BioTime, Inc. for the last five fiscal years beginning December 31, 2010 to two indices: the NYSE Amex Market Value – U.S. Companies (“Amex Market Value”) and the NYSE Arca Biotechnology Index. The total return for our common shares and for each index assumes the reinvestment of dividends, although we have never declared dividends on BioTime common shares, and is based on the returns of the component companies weighted according to their capitalizations as of the end of each quarterly period. The Amex Market Value tracks the aggregate price performance of equity securities of U.S. companies listed therein. The NYSE Arca Biotechnology Index represents biotechnology companies, trading on NYSE MKT under the Standard Industrial Classification (“SIC”) Code Nos. 283 (Drugs) and 382 (Laboratory Apparatus and Analytical, Optical) main categories (2834:Pharmaceutical Preparations; 2835: Diagnostic Substances; 2836: Biological Products; 3826: Laboratory Analytical Instruments; and 3829: Measuring & Controlling Devices). BioTime common stock trades on the NYSE MKT and is a component of the NYSE Amex Market Value – US Companies.

Comparison of Five-Year Cumulative Total Return on Investment

		2010	2011	2012	2013	2014	2015
BioTime, Inc.	Return %		-30.25	-45.96	14.65	3.61	9.92
	Cum \$	100.00	69.75	37.70	43.22	44.78	49.22
AMEX Market Value (US Companies)	Return %		-8.77	9.84	10.23	5.09	-22.23
	Cum \$	100.00	91.23	100.21	110.47	116.09	90.28
NYSE Arca Biotechnology Index	Return %		-15.84	41.88	50.80	47.91	11.39
	Cum \$	100.00	84.16	119.40	180.06	266.33	296.67

BioTime, Inc., the Amex Market Value and NYSE Arca Biotechnology Index⁽²⁾

This Section is not “soliciting material,” is not deemed “filed” with the SEC and is not to be incorporated by reference in any filing of BioTime under the Securities Act of 1933, or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing. Shows the (1) cumulative total return on investment assuming an investment of \$100 in each of BioTime, Inc., the Amex Market Value and the NYSE Arca Biotechnology Index on December 31, 2010. The cumulative total return on BioTime common shares has been computed based on a price of \$8.33 per share, the price at which BioTime’s common shares closed on December 31, 2010.

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Item 6. Selected Financial Data

BIOTIME, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Year Ended December 31,				
	2015	2014	2013	2012	2011
REVENUES:					
Subscription and advertisement revenues	1,357	\$ 1,173	\$ 2,218	\$ 900	\$ 264
Royalties from product sales	719	398	367	542	757
Grant income	4,502	3,297	1,573	2,222	2,767
Sales of research products and services	458	376	276	251	646
Total revenues	7,036	5,244	4,434	3,915	4,434
Cost of sales	(1,107)	(837)	(793)	(434)	(79)
Gross Profit	5,929	4,407	3,641	3,481	4,355
OPERATING EXPENSES:					
Research and development	(42,604)	(37,533)	(26,609)	(18,117)	(13,700)
Acquired in-process research and development ⁽¹⁾	-	-	(17,459)	-	-
General and administrative	(29,134)	(17,556)	(15,559)	(10,365)	(9,342)
Total operating expenses	(71,738)	(55,089)	(59,627)	(28,482)	(23,042)
Loss from operations	(65,809)	(50,682)	(55,986)	(25,001)	(18,687)
OTHER INCOME/(EXPENSE):					
Interest income/(expense), net	(340)	(89)	-	19	30
Loss on equity method investment	(35)	-	-	-	-
Gain on equity investment	3,694	-	-	-	-
Other (expense)/income, net	(160)	(384)	(204)	(325)	213
Total other (expenses)/income, net	3,159	(473)	(204)	(305)	243
LOSS BEFORE INCOME TAX BENEFITS	(62,650)	(51,155)	(56,190)	(25,306)	(18,444)
Deferred income tax benefit	4,516	7,376	3,281	-	-
NET LOSS	(58,134)	(43,779)	(52,909)	(25,306)	(18,444)
Net loss attributable to non-controlling interest	11,143	7,367	9,026	3,880	1,928
NET LOSS ATTRIBUTABLE TO BIOTIME, INC.	(46,991)	(36,412)	(43,883)	(21,426)	(16,516)
Dividends on preferred shares	(415)	(87)	-	-	-
NET LOSS ATTRIBUTABLE TO BIOTIME, INC. COMMON SHAREHOLDERS	\$(47,406)	\$(36,499)	\$(43,883)	\$(21,426)	\$(16,516)
Foreign currency translation gain/(loss)	(424)	125	119	63	(1,020)
Unrealized gain on available-for-sale securities	1	(2)	3	-	-
COMPREHENSIVE LOSS ATTRIBUTABLE TO BIOTIME, INC. COMMON SHAREHOLDERS BEFORE PREFERRED STOCK DIVIDEND	\$(47,414)	\$(36,289)	\$(43,761)	\$(21,363)	\$(17,536)

BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (0.59)	\$ (0.55)	\$ (0.81)	\$ (0.44)	\$ (0.35)
WEIGHTED AVERAGE NUMBER OF COMMON STOCK OUTSTANDING:BASIC AND DILUTED	79,711	66,467	54,226	49,214	47,054

Represents the value of incomplete research and development projects acquired by Asterias from Geron under the (1) Asset Contribution Agreement which Asterias intends to continue. See Note 2 to the Consolidated Financial Statements.

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	December 31,				
	2015	2014	2013	2012	2011
Consolidated Balance Sheet Data					
(in thousands):					
Cash and cash equivalents	\$42,229	\$29,487	\$5,495	\$4,350	\$22,212
Total assets	94,660	74,901	57,730	29,749	45,830
Total liabilities	18,213	12,178	15,467	5,454	4,372
Accumulated deficit	(229,181)	(182,190)	(145,778)	(101,896)	(80,470)
Total shareholder's equity	\$76,447	\$62,723	\$42,262	\$24,294	\$41,458

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the two-year period ended December 31, 2015, and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the year ended December 31, 2015 as compared to the year ended December 31, 2014, and during the year ended December 31, 2014 as compared to the year ended December 31, 2013. This discussion should be read in conjunction with our consolidated financial statements for the two-year period ended December 31, 2015 and related notes included elsewhere in this Annual Report on Form 10-K. These historical financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this filing, particularly in "Item 1A. Risk Factors."

Critical Accounting Policies

Revenue recognition – We comply with ASC 605-10 and recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. Grant income and the sale of research products and services are recognized as revenue when earned. Revenues from the sale of research products and services are primarily derived from the sale of hydrogels and stem cell products. Royalty revenues consist of product royalty payments. License fee revenues consist of fees under license agreements and are recognized when earned and reasonably estimable and also include subscription and advertising revenue from our online databases based upon respective subscription or advertising periods. We recognize revenue in the quarter in which the royalty reports are received rather than the quarter in which the sales took place. When we are entitled to receive up-front nonrefundable licensing or similar fees pursuant to agreements under which we have no continuing performance obligations, the fees are recognized as revenues when collection is reasonably assured. When we receive up-front nonrefundable licensing or similar fees pursuant to agreements under which we do have continuing performance obligations, the fees are deferred and amortized ratably over the performance period. If the performance period cannot be reasonably estimated, we amortize nonrefundable fees over the life of the contract until such time that the performance period can be more reasonably estimated. Milestone payments, if any, related to scientific or technical achievements are recognized in income when the milestone is accomplished if (a) substantive effort was required to achieve the milestone, (b) the amount of the milestone payment appears reasonably commensurate with the effort expended, and (c) collection of the payment is reasonably assured.

Patent costs – Costs associated with obtaining patents on products or technology developed are expensed as general and administrative expenses when incurred.

Investments in Common Stock of Privately Held Companies – BioTime evaluates whether investments held in common stock of an investee is a variable interest entity ("VIE") and, if so, whether BioTime is the primary beneficiary of the VIE, in order to determine whether consolidation of the VIE is required in accordance with accounting guidance for consolidations under Accounting Standards Codification ("ASC") 810-10. If the investee is determined not to be a VIE, then the investee is evaluated under the Voting Interest model, to determine whether BioTime has a controlling financial interest and consolidation of the entity is required. If consolidation of the entity is not required under either the VIE assessment or the Voting Interest model, the investment is evaluated to determine if the equity method of accounting should be applied in accordance with ASC 323, Investments – Equity Method and Joint Ventures. The equity method applies to investments in common stock or in substance common stock where BioTime exercises significant influence over, but does not control, the investee, typically represented by ownership of 20% or more of

the voting interests of an entity.

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BioTime initially records equity method investments at fair value on the date of the acquisition with subsequent adjustments to the investment balance based on BioTime's share of earnings or losses from the investment included in other income or expenses, net, on the consolidated statements of operations. The equity method investment balance is shown in noncurrent assets of the consolidated balance sheets.

BioTime reviews investments accounted for under the equity method for impairment whenever events or changes in circumstances indicate that the carrying amount of the investment may not be fully recoverable. If a determination is made that an other-than-temporary impairment exists, BioTime writes down its investment to fair value.

Intangible assets, net – Intangible assets with finite useful lives are amortized over estimated useful lives and intangible assets with indefinite lives are not amortized but rather are tested at least annually for impairment. Acquired in-process research and development intangible assets are accounted depending on whether they were acquired as part of an acquisition of a business, or assets that do not constitute a business. When acquired in conjunction with acquisition of a business, these assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts and are capitalized as an asset. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. However, when acquired in conjunction with an acquisition of assets that do not constitute a business (such as Asterias' acquisition of assets from Geron), in accordance with the accounting rules in ASC 805-50, such intangible assets related to in process research and development ("IPR&D") are expensed upon acquisition.

Research and development – Research and development costs are expensed when incurred, and consist principally of salaries, payroll taxes, consulting fees, research and laboratory fees, and license fees paid to acquire patents or licenses to use patents and other technology from third parties.

Stock-based compensation – We have adopted accounting standards governing share-based payments, which require the measurement and recognition of compensation expense for all share-based payment awards made to directors and employees, including employee stock options, based on estimated fair values. We utilize the Black-Scholes Merton option pricing model. Our determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. The expected term of options granted is derived from historical data on employee exercises and post-vesting employment termination behavior. The risk-free rate is based on the U.S. Treasury rates in effect during the corresponding period of grant. Although the fair value of employee stock options is determined in accordance with recent FASB guidance, changes in the subjective assumptions can materially affect the estimated value. In management's opinion, the existing valuation models may not provide an accurate measure of the fair value of employee stock options because the option-pricing model value may not be indicative of the fair value that would be established in a willing buyer/willing seller market transaction.

Treasury stock – We account for BioTime common shares issued to subsidiaries for future potential working capital needs as treasury stock on the consolidated balance sheet. We have the intent and ability to register any unregistered shares to support the marketability of the shares.

Impairment of long-lived assets – Our long-lived assets, including intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. If an impairment indicator is present, we evaluate recoverability by a comparison of the carrying amount of the assets to future undiscounted net cash flows expected to be generated by the assets. If the assets are impaired, the impairment recognized is measured by the amount by which the carrying amount exceeds the estimated fair value of the assets.

Deferred license and consulting fees – Deferred license and consulting fees consist of the value of warrants issued to third parties for services, and deferred license fees paid to acquire rights to use the proprietary technologies of third parties. The value of the warrants is being amortized over the lives of the warrants, and deferred license fees over the estimated useful lives of the licensed technologies or licensed research products. We are applying a 10 year estimated useful life to the technologies and products that we are currently licensing. The estimation of the useful life any technology or product involves a significant degree of inherent uncertainty, since the outcome of research and development or the commercial life of a new product cannot be known with certainty at the time that the right to use the technology or product is acquired. We will review the continued appropriateness of the 10 year estimated useful life for impairments that might occur earlier than the original expected useful lives.

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Royalty Obligation and Deferred license fees – Deferred license and consulting fees consist of the value of warrants issued to third parties for services, and deferred license fees paid to acquire rights to use the proprietary technologies of third parties. The value of the warrants is being amortized over the lives of the warrants, and deferred license fees over the estimated useful lives of the licensed technologies or licensed research products. We are applying a 10 year estimated useful life to the technologies and products that we are currently licensing. The estimation of the useful life of any technology or product involves a significant degree of inherent uncertainty, since the outcome of research and development or the commercial life of a new product cannot be known with certainty at the time that the right to use the technology or product is acquired. We will review the continued appropriateness of the 10 year estimated useful life for impairments that might occur earlier than the original expected useful lives.

Principles of consolidation – Our consolidated financial statements include the accounts of our wholly-owned subsidiary ESI, and the accounts of our majority owned subsidiaries, Asterias, ReCyte Therapeutics, OncoCyte, OrthoCyte, BioTime Asia, Cell Cure Neurosciences, and LifeMap Sciences. All material intercompany accounts and transactions have been eliminated in consolidation. The consolidated financial statements are presented in accordance with accounting principles generally accepted in the U.S. and with the accounting and reporting requirements of SEC Regulation S-X.

Results of Operations

Comparison of Years Ended December 31, 2015 and 2014 (in thousands).

Revenues

The following tables show our revenues for the years ended December 31, 2015 and 2014 (in thousands).

	Year Ended		\$	%
	December 31,		Increase/	Increase/
	2015	2014	Decrease	Decrease
Subscription and advertising revenue	\$ 1,357	\$ 1,173	\$ +184	+16%
Royalty from product sales	719	398	+321	+81%
Grant income	4,502	3,297	+1,205	+37%
Sales of research products and services	458	376	+82	+22%
Total revenues	7,036	5,244	+1,792	+34%
Cost of sales	(1,107)	(837)	+270	+32%
Gross Profit	5,929	4,407	+1,522	+35%

	Three Months		\$	%
	Ended		Increase/	Increase/
	December 31,	December 31,	Decrease	Decrease
	2015	2014		
Subscription and advertising revenue	\$337	\$292	\$ +45	+15%
Royalty from product sales	88	76	+12	+16%
Grant income	906	1,443	-537	-37%
Sales of research products and services	130	76	+54	+71%
Total revenues	1,461	1,887	-426	-23%
Cost of sales	(150)	(223)	-73	-33%
Gross Profit	1,311	1,664	-353	-21%

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Our license fee revenues amounted to \$1.4 million and \$1.2 million for the years ended December 31, 2015 and 2014, respectively. License fee revenue entirely represent subscription and advertising revenues from LifeMap Science's online database business primarily related to its GeneCards® database.

Our royalty revenues from product sales for the years ended December 31, 2015 and 2014 include \$719,000 and \$398,000 respectively, of royalties on sales of products, including \$535,000 of royalties paid to Asterias primarily by GE Healthcare and Stem Cell Technologies, Inc. and \$184,000 of royalties paid to BioTime by Hospira, CJ Health and Millipore. Royalties from Hospira from the sale of Hextend® are due ninety (90) days after the end of each calendar quarter and are recognized as revenue during the quarter in which we receive payment or a royalty report from Hospira.

Total grant revenue in 2015 increased by approximately 37% primarily due to recognition of \$3.0 million of the \$14.3 million CIRM grant awarded to Asterias in 2014. Grant revenue for the years ended December 31, 2015 and 2014 also include \$456,000 and \$656,000, respectively, from various grants awarded to us by the National Institutes of Health ("NIH") and \$1.0 million and \$1.6 million, respectively, of grants from the Office of the Chief Scientist of Israel ("OCS") recognized through Cell Cure Neurosciences. All of the NIH grants expired as of December 31, 2015.

Revenues from the sale of research products and services are primarily derived from the sale of hydrogels and stem cell products by our ESI-BIO division. During December 2015, we contributed or licensed rights to sell those research products in exchange for our equity method investment in Ascendance.

Expenses

The following tables show our operating expenses for the years ended December 31, 2015 and 2014 (in thousands).

	Year Ended		\$	%
	December 31,		Increase/	Increase/
	2015	2014	Decrease	Decrease
Research and development expenses	\$(42,604)	\$(37,533)	\$+5,071	+14%
General and administrative expenses	(29,134)	(17,556)	+11,578	+66%
Interest expense, net	(340)	(89)	+251	+282%
Gain on equity method investment	3,694	-	3,694	-%
BioTime's share of losses in equity method investment in Ascendance	(35)	-	+35	-%
Other expense, net	(160)	(384)	-224	-58%

	Three Months		\$	%
	Ended		Increase/	Increase/
	December 31,		Decrease	Decrease
	2015	2014		
Research and development expenses	\$(12,789)	\$(11,277)	\$+1,512	+13%
General and administrative expenses	(10,220)	(4,792)	+5,428	+113%
Interest income/(expense), net	133	(58)	-75	-129%
Gain on equity method investment	3,694	-	+3,694	-%
BioTime's share of losses in equity method investment in Ascendance	(35)	-	+35	-%
Other income/(expense), net	244	(514)	-758	-147%

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Research and development expenses – Research and development expenses increased by \$5.1 million. The increase is primarily attributable to the following increases in expense: \$4.2 million of consulting and outside research and services, including stock-based compensation to consultants, primarily related to regulatory and clinical trials of Asterias' AST-OPC1 and OncoCyte's cancer diagnostic tests; \$3.2 million of employee compensation, including stock-based compensation and related costs; \$254,000 of rent and facilities maintenance related expenses; \$226,000 of travel, meals and entertainment related expenses; \$183,000 of recruiting expenses; \$141,000 of equipment rental and equipment maintenance related expenses; \$118,000 in laboratory expenses and supplies; \$82,000 in telephone and online expenses allocated to research and development expenses; \$80,000 in insurance expenses allocated to research and development expense; and a net increase \$282,000 in miscellaneous other expenses. These increases were in part offset by a reduction of \$2.1 million of amortization of intangible assets, \$1.2 million of Cell Cure Neurosciences related expenses, \$173,000 in contract manufacturing related expenses and \$59,000 of ESI related expenses.

The following table shows the approximate amounts and percentages of our total research and development expenses of \$42.6 million and \$37.5 million allocated to our primary research and development programs during the years ended December 31, 2015 and 2014, respectively (in thousands).

Company	Program	Amount ⁽¹⁾		Percent	
		2015	2014	2015	2014
Asterias					
Biotherapeutics ⁽²⁾	hES-based cell therapy programs	\$ 17,322	\$ 13,310	40.7%	35.5%
BioTime and ESI	PureStem [®] hEPCs, cGMP hES cell lines, and related research products	\$ 5,196	\$ 4,089	12.2%	10.9%
BioTime	Hydrogel products and HyStem [®] research	\$ 4,047	\$ 5,177	9.5%	13.8%
BioTime	Hextend [®]	\$ 59	\$ 71	0.1%	0.2%
BioTime	HyStem [®] 3D cell culture platform for cancer drug discovery	\$ -	\$ 100	-	0.3%
Cell Cure					
Neurosciences	OpRegen [®] and neurological disease therapies	\$ 4,086	\$ 5,311	9.6%	14.1%
LifeMap Sciences ⁽²⁾	Databases and mHealth products	\$ 5,251	\$ 3,567	12.3%	9.5%
OncoCyte	Cancer diagnostics	\$ 4,911	\$ 3,873	11.5%	10.3%
OrthoCyte	Orthopedic therapy	\$ 590	\$ 693	1.4%	1.8%
ReCyte Therapeutics	Cardiovascular therapy	\$ 1,142	\$ 1,342	2.7%	3.6%
Total		\$ 42,604	\$ 37,533	100.0%	100.0%

Amount also includes research and development expenses incurred directly by the subsidiary and certain general research and development expenses, such as lab supplies, lab expenses, rent allocated, and insurance allocated to research and development expenses, incurred directly by BioTime on behalf of the subsidiary and allocated to the subsidiary.

(2) Includes LifeMap Solutions

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General and administrative expenses – General and administrative expenses for the years ended December 31, 2015 and 2014 increased by \$11.6 million primarily attributable to the following increases: \$5.2 million of employee compensation, including employee bonus accruals, stock-based compensation and related costs; \$1.2 million of legal expenses; \$1.1 million of general consulting expenses; \$879,000 of investor and public relations related expenses; \$648,000 of recruiting expenses; \$555,000 of stock-based compensation to consultants; \$861,000 of accounting, audit and tax related expense; \$433,000 of cash and stock-based compensation to our independent directors; \$201,000 of travel, meals and entertainment expenses; \$162,000 in seminar, conference, and meeting expenses; \$137,000 in office expenses and supplies; \$104,000 in facilities and equipment rent and maintenance related expenses; and a net increase of \$385,000 of miscellaneous other expenses. These increases were in part offset by a reduction of \$119,000 of Cell Cure Neurosciences' related expenses.

General and administrative expenses include employee and director compensation allocated to general and administrative expenses, consulting fees other than those paid for science-related consulting, facilities and equipment rent and maintenance related expenses, insurance costs allocated to general and administrative expenses, stock exchange-related costs, depreciation expense, shipping expenses, marketing costs, legal and accounting costs, and other miscellaneous expenses which are allocated to general and administrative expense.

The following table shows the amount and approximate percentages of our total general and administrative expenses of \$29.1 million and \$17.6 million allocated to BioTime and our subsidiaries during the years ended December 31, 2015 and 2014, respectively (in thousands).

Company	Amount ⁽¹⁾		Percent	
	2015	2014	2015	2014
BioTime	\$9,752	\$7,130	33.5%	40.6%
Asterias Biotherapeutics	\$7,711	\$5,280	26.5%	30.1%
BioTime Asia	\$9	\$12	-	0.1%
Cell Cure Neurosciences	\$655	\$723	2.2%	4.1%
ESI	\$245	\$199	0.9%	1.1%
LifeMap Sciences ⁽²⁾	\$5,142	\$2,554	17.6%	14.5%
OncoCyte	\$4,278	\$870	14.7%	5.0%
OrthoCyte	\$582	\$383	2.0%	2.2%
ReCyte Therapeutics	\$760	\$405	2.6%	2.3%
Total	\$29,134	\$17,556	100.0%	100.0%

(1) Amount includes general and administrative expenses incurred directly by the subsidiary and allocations from BioTime for certain general overhead expenses.

(2) Includes LifeMap Solutions

Interest income/(expense) – During 2015, we earned \$125,000 of interest income, net of \$466,000 of interest expense. During 2014, we earned \$2,600 of interest income, net of \$91,000 of interest expense. Interest income is primarily attributed to interest earned on cash balances held in interest bearing accounts during their respective years.

Gain on equity method investment– This gain was generated on the sale of a certain group of assets as part of our equity method investment in Ascendance.

BioTime's share of losses in equity method investment – During 2015, we recognized \$35,000 in our share of losses from our equity method investment.

Other income/(expense) – Other expenses in 2015 consist primarily of foreign currency transaction gains and losses recognized by ESI and by Cell Cure Neurosciences. Other expenses in 2014 consist primarily of discount on convertible loan of \$56,000, charitable donations of \$36,000, \$24,000 in income tax provision for LifeMap Sciences, Ltd, one of our majority owned subsidiaries, and \$338,000 of foreign currency transaction loss.

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Comparison of Years Ended December 31, 2014 and 2013 (in thousands)

The following tables show our revenues for the years ended December 31, 2014 and 2013 (in thousands).

Revenues

	Year Ended		\$	%
	December 31,		Increase/	Increase/
	2014	2013	Decrease	Decrease
License fees	\$1,173	\$2,218	\$-1,045	-47%
Royalty from product sales	398	367	+31	+8%
Grant income	3,297	1,573	+1,724	+110%
Sales of research products and services	376	276	+100	+36%
Total revenues	5,244	4,434	+810	+18%
Cost of sales	(837)	(793)	+44	+6%
Gross Profit	4,407	3,641	+766	+21%

	Three Months		\$	%
	Ended		Increase/	Increase/
	December 31,		Decrease	Decrease
	2014	2013		
License fees	\$292	\$1,123	\$-831	-74%
Royalty from product sales	76	75	+1	+1%
Grant income	1,443	632	+811	+128%
Sales of research products and services	76	62	+14	+23%
Total revenues	1,887	1,892	-5	-%
Cost of sales	(223)	(222)	+1	-%
Gross Profit	1,664	1,670	-6	-%

License fee revenues for the years ended December 31, 2014 and 2013 include subscription and advertising revenues of \$1,172,680 and \$1,317,000, respectively, from LifeMap Science's online database business primarily related to its GeneCards® database. License fee revenue of \$2,218,174 for the year ended December 31, 2013 included accelerated amortization of all remaining upfront license fees from certain licenses related to the development of our blood plasma volume expander products Hextend® and PentaLyte® in certain foreign countries, which terminated in 2013.

Our royalty revenues from product sales for the years ended December 31, 2014 and 2013 include \$208,238 and \$366,492 respectively, of royalties on sales of Hextend® made by Hospira and CJ Health and \$189,215 and nil, respectively, of royalties earned by Asterias. Royalties on sales of Hextend® have been decreasing as hospitals have shifted their purchases of blood volume expanders to albumin products, leading to a decline in the number of units sold and the price per unit. Sales of Hextend® also declined following the implementation of certain new safety labeling changes mandated by the FDA during November 2013 for the entire class of hydroxyethyl starch products, including Hextend®. In addition, during June 2014, we entered into an amendment of our license agreement with CJ Health that extended the term of the license and CJ Health's royalty payment obligation beyond the expiration date of our Korean patents but reduced the royalty rate by 50%. We expect royalty revenues from sales of Hextend® to continue to decline as a percentage of total revenue. Under our license agreements with Hospira and CJ Health, our licensees report sales of Hextend® and pay us the royalties due on account of such sales within 90 days after the end of each calendar quarter. We recognize such revenues in the quarter in which the sales report is received, rather than the quarter in which the sales took place. For example, royalties on sales made during the first quarter 2014 were not recognized until the second quarter of fiscal year 2014.

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Total grant revenue in 2014 increased by approximately 110% primarily due to recognition of \$1,034,456 of the \$14.3M CIRM grant awarded to Asterias in 2014. Grant revenue for the years ended December 31, 2014 and 2013 also include \$656,125 and \$221,594, respectively from various grants awarded to us by the National Institutes of Health (“NIH”) and \$1,606,251 and \$1,333,901, respectively recognized through Cell Cure Neurosciences. Two of the five NIH grants expired in September 2014 while the other three more recently awarded grants expired on various dates in 2015.

Revenues from the sale of research products and services are primarily derived from the sale of hydrogels and stem cell products.

While revenues increased by 18% during the year ended December 31, 2014, cost of sales increased by only 6%, reflecting the fact that grant and amortization of upfront license fee revenues, which do not give rise to costs of sales, increased by \$822,337.

Expenses

The following tables show our operating expenses for the years ended December 31, 2014 and 2013 (in thousands).

	Year Ended		\$	%
	December 31,		Increase/	Increase/
	2014	2013	Decrease	Decrease
Research and development expenses	\$(37,533)	\$(26,609)	\$+10,924	+41%
Acquired in-process research and development expenses	-	(17,459)	-17,459	-100%
General and administrative expenses	(17,556)	(15,559)	+1,997	+13%
Interest income/(expense)	(89)	-	+89	-%
Other expense, net	(375)	(209)	+166	+79%

	Three Months Ended		\$	%
	December 31,		Increase/	Increase/
	2014	2013	Decrease	Decrease
Research and development expenses	\$(11,277)	\$(9,220)	\$+2,057	+22%
Acquired in-process research and development expenses	-	(17,459)	-17,459	-100%
General and administrative expenses	(4,792)	(4,285)	+507	+12%
Interest income/(expense)	(58)	(3)	+55	+1,800%
Other expense, net	(514)	(40)	+474	+1,200%

Research and development expenses – Research and development expenses increased by \$10,923,201. The increase is largely due to the amortization of intangible assets acquired by Asterias from Geron and BioTime in October 2013 and the ramp-up of the Asterias and LifeMap Solutions product development programs. OncoCyte’s clinical trial work to develop its cancer diagnostics and our continued clinical development of Renevia® also contributed to the increase in research and development expense. Amortization of intangible assets increased by \$4,063,974, employee compensation, including stock-based compensation and related costs allocated to research and development expenses increased by \$3,638,783, contract manufacturing related expenses increased by \$1,083,697, patent, license, and trademark related fees increased by \$949,431, outside research and services primarily related to our regulatory, preclinical and clinical trials of Renevia®, AST-OPC1, and OncoCyte cancer diagnostics increased by \$726,977, rent and facilities maintenance related expenses allocated to research and development increased by \$533,668, depreciation expenses allocated to research and development increased by \$365,517, laboratory and supplies expenses increased by \$390,063, insurance premiums allocated to research and development expenses increased by \$171,911, and travel and entertainment related expenses increased by \$112,354. These increases are in part offset by a decrease of \$1,119,352 in Cell Cure related expenses and a decrease of \$161,303 in ESI related expenses.

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The following table shows the approximate amounts and percentages of our total research and development expenses of \$37,532,624 and \$26,609,423 allocated to our primary research and development projects during the years ended December 31, 2014 and 2013, respectively (in thousands).

Company	Program	Amount ⁽¹⁾		Percent	
		2014	2013	2014	2013
Asterias					
Biotherapeutics ⁽²⁾	hES cell-based cell therapy programs	\$13,310	\$4,319	35.5%	16.2%
BioTime Asia	Stem cell products for research	\$-	\$31	-%	0.1%
BioTime	PureStem [®] technology	\$-	\$227	-%	0.9%
BioTime	Hextend [®]	\$71	\$90	0.2%	0.3%
BioTime	3D Culture	\$100	\$50	0.3%	0.2%
	PureStem [®] hEPCs, cGMP hES cell lines, and related research products	\$4,089	\$2,764	10.9%	10.4%
BioTime	Hydrogel products and HyStem [®] research	\$5,177	\$5,229	13.8%	19.6%
Cell Cure					
Neurosciences	OpRegen [®] and neurological disease therapies	\$5,311	\$6,402	14.1%	24.1%
LifeMap Sciences ⁽³⁾	Database development and mHealth products	\$3,567	\$2,663	9.5%	10.0%
OncoCyte	Cancer diagnostics	\$3,873	\$2,761	10.3%	10.4%
OrthoCyte	Orthopedic therapy	\$693	\$1,030	1.8%	3.9%
ReCyte Therapeutics	Cardiovascular therapy	\$1,342	\$1,042	3.6%	3.9%
Total		\$37,533	\$26,608	100.0%	100.0%

(1) Amount also includes research and development expenses incurred directly by the subsidiary and certain general research and development expenses, such as lab supplies, lab expenses, rent allocated, and insurance allocated to research and development expenses, incurred directly by BioTime on behalf of the subsidiary and allocated to the subsidiary.

(2) Excludes IPR&D expenses related to intangible assets acquired from Geron. IPR&D represents the value of incomplete research and development projects which Asterias intends to continue. See Note 2 to the Consolidated Financial Statements.

(3) Includes LifeMap Solutions during 2014.

General and administrative expenses – General and administrative expenses for the years ended December 31, 2014 and 2013 were \$17,556,102 and \$15,558,674, respectively. The increase of \$1,997,428 in total general and administrative costs on a consolidated basis for the year ended December 31, 2014 is primarily attributable to an increase of \$1,802,661 in employee compensation, including employee bonus accruals, stock-based compensation and related costs allocated to general and administrative expenses, an increase of \$309,002 in general consulting expenses, an increase of \$262,443 in marketing and advertisement related expenses, an increase of \$303,741 in accounting, audit and tax related expense, an increase of \$172,036 in Asterias' state corporation and franchise taxes, an increase of \$116,614 in rent and facilities maintenance related expenses allocated to general and administrative expenses, an increase of \$116,750 in outside directors compensation expenses, an increase in \$111,155 in investor and public relations related expenses and an increase of \$95,873 in travel, lodging and meals allocated to general and administrative expenses. These increases are in part offset by decreases of \$711,108 in legal fees generally reflecting non-recurring expenses that we incurred in 2013 related to the Asset Contribution Agreement transactions, including preparing registration statements for filing with the SEC and a proxy statement for a special meeting of our shareholders, a decrease of \$346,951 in stock-based compensation to consultants and our independent directors, a decrease of \$142,087 in office expenses and supplies and computer supplies, and a decrease of \$70,291 in ESI related expenses.

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General and administrative expenses include employee and director compensation allocated to general and administrative expenses, consulting fees other than those paid for science-related consulting, insurance costs allocated to general and administrative expenses, stock exchange-related costs, depreciation expense, shipping expenses, marketing costs, legal and accounting costs, and other miscellaneous expenses which are allocated to general and administrative expense.

The following table shows the amount and approximate percentages of our total general and administrative expenses of \$17,556,102 and \$15,558,674 allocated to BioTime and our subsidiaries during the years ended December 31, 2014 and 2013, respectively (in thousands).

Company	Amount ⁽¹⁾		Percent	
	2014	2013	2014	2013
BioTime	\$7,130	\$7,366	40.6%	47.3%
Asterias Biotherapeutics	\$5,280	\$3,883	30.1%	25.0%
BioTime Asia	\$12	\$164	0.1%	1.1%
Cell Cure Neurosciences	\$723	\$676	4.1%	4.3%
ESI	\$199	\$306	1.1%	2.0%
LifeMap Sciences	\$2,554	\$1,995	14.5%	12.8%
OncoCyte	\$870	\$408	5.0%	2.6%
OrthoCyte	\$383	\$381	2.2%	2.5%
ReCyte Therapeutics	\$405	\$378	2.3%	2.4%
Total	\$17,556	\$15,557	100.0%	100.0%

(1) Amount includes general and administrative expenses incurred directly by the subsidiary and allocations from BioTime for certain general overhead expenses.

Interest income/(expense) – During 2014, we earned \$2,551 of interest income, net of \$91,047 of interest expense. During 2013, we earned \$2,512 of interest income, net of \$3,090 of interest expense. Interest income is primarily attributed to interest earned on cash balances held in interest bearing accounts during their respective years.

Other income/(expense) – Other expenses in 2014 consists primarily of amortization of discount on convertible loan of \$56,320, charitable donations of \$36,261, \$24,124 in income tax provision for LifeMap Sciences, Ltd, one of our majority owned subsidiaries, and \$338,076 of foreign currency transaction loss. Other expenses in 2013 consists primarily of charitable donations of \$42,500, \$45,461 in income tax provision for LifeMap Sciences, Ltd, one of our majority owned subsidiaries, and \$133,479 of foreign currency transaction loss.

Taxes

Income Taxes – A deferred income tax benefit of \$4.5 million was recorded for the year ended December 31, 2015, of which \$4.8 million was related to the federal benefit and \$290,000 was related to state tax expense. A deferred income tax benefit of \$7.4 million was recorded for the year ended December 31, 2014, of which \$5.2 million of the benefit was related to federal and \$2.2 million was related to state taxes. As disclosed in Note 14 to the Consolidated Financial Statements, Asterias established deferred tax liabilities primarily related to its acquisition of certain intellectual property. It is more likely than not that the Asterias deferred tax assets are fully realizable since these income tax benefits are expected to be available to offset such Asterias deferred tax liabilities. As BioTime and Asterias file separate tax returns, they may not use each other's tax attributes. Accordingly, BioTime has established a valuation allowance only pertaining to its deferred tax assets presented in the consolidated balance sheet as of December 31, 2015 and 2014.

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Liquidity and Capital Resources

At December 31, 2015, we had \$42.2 million of cash and cash equivalents on hand of which \$22.1 million was held by subsidiaries.

We have outstanding warrants to purchase 10,109,860 of our common shares at an exercise price of \$4.55 per share of which 714,998 expired in January 2016 and the rest will expire on dates ranging from June 5, 2018 through September 30, 2018. We will receive \$42.7 million if all of the warrants excluding those that expired in January 2016 are exercised. There can be no assurance that the warrants will be exercised.

Asterias was awarded a \$14.3 million Strategic Partnership III grant by CIRM to help fund its clinical development of AST-OPC1 in 2014. The grant will provide funding for Asterias to conduct a Phase I/IIa clinical trial of AST-OPC1 in subjects with complete cervical spinal cord injury, and for product development efforts to refine and scale manufacturing methods to support eventual commercialization. CIRM will disburse the grant funds to Asterias through July 1, 2018 in accordance with a quarterly disbursement schedule, subject to Asterias attaining certain progress and safety milestones. Asterias has received approximately \$6.6 million in additional installment payments from CIRM from 2014 through December 31, 2015. As the balance of the distributions of the CIRM grant are subject to meeting certain progress and go/no-go milestones, there can be no assurance that Asterias will receive the entire amount granted.

During September 2014, Asterias entered into the CRUK Agreement pursuant to which CRUK has agreed to fund Phase I/IIa clinical development of Asterias' AST-VAC2 product candidate. Asterias will, at its own cost, complete process development and manufacturing scale-up of the AST-VAC2 manufacturing process and will transfer the resulting cGMP compatible process to CRUK. CRUK will, at its own cost, manufacture the clinical grade AST-VAC2 and will carry out the Phase I/IIa clinical trial of AST-VAC2 in cancer patients both resected early-stage and advanced forms of lung cancer.

OrthoCyte has entered into a Research and Development Agreement and a Licensing Agreement with Heraeus. Under the terms of those agreements, OrthoCyte will undertake a development program for cell-based bone grafting products. Heraeus has agreed to make payments to OrthoCyte upon the attainment of certain product development milestones, and royalties on product sales if any products are successfully developed, registered with regulatory authorities and commercialized, including payment of all costs associated with product development activities through the submission of an investigational new drug application. As of December 31, 2015, none of the milestones were achieved but we received \$1.0 million upfront license fee payment of which \$77,000 was recognized as revenues and the remaining in deferred revenues in our consolidated financial statements.

Since inception, we have incurred significant net losses and have funded its operations primarily through the issuance of equity securities, payments from research grants, royalties from product sales and sales of research products and services. At December 31, 2015, we had an accumulated deficit of \$229.2 million, working capital of \$34.8 million and shareholders' equity of \$76.4 million. We have evaluated projected cash flows for us and our subsidiaries and we believe that our consolidated cash, cash equivalents, and available for sale securities of \$43.0 million as of December 31, 2015, will be sufficient to fund our operations at least through 2016. However, clinical trials being conducted by Asterias and Cell Cure Neurosciences will be funded in part with funds from grants and not from cash on hand. If Asterias or Cell Cure Neurosciences were to lose its grant funding it may be required to delay, postpone, or cancel its clinical trials or limit the number of clinical trial sites, or otherwise reduce or curtail its operations unless it is able to obtain from another source of adequate financing that could be used for its clinical trial. OncoCytel will need to raise additional capital during 2016 if, based on the results of its research and development efforts, it determines to establish a CLIA laboratory and commence marketing its first cancer diagnostic test.

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Cash generated by operations

During the year ended December 31, 2015, we received \$9.9 million of cash in our operations. Our sources of cash during 2015 primarily consisted of \$2.0 million from the sale of research products and subscription and advertisement revenues and research grants payments of \$1.0 million to Cell Cure Neurosciences, \$5.6 million to Asterias, and \$577,000 from the NIH. We also received \$719,000 in royalty revenues on product sales by licensees. During the year ended December 31, 2014, we received \$3.9 million of cash in our operations. Our sources of cash during 2014 primarily consisted of \$1.2 million from the sale of research products and subscription and advertisement revenues and research grants payments of \$1.8 million to Cell Cure Neurosciences, \$917,000 to Asterias, and \$531,000 to us from the NIH. We also received \$397,000 in royalty revenues on product sales by licensees.

Cash used in operations

During 2015, our total research and development expenditures were \$42.6 million and our general and administrative expenditures were \$29.1 million. Net loss attributable to BioTime for the year ended December 31, 2015 amounted to \$47.0 million. Net cash used in operating activities during this period amounted to \$44.5 million. The difference between the net loss and net cash used in operating activities during the year ended December 31, 2015 was primarily attributable to \$11.1 million of stock-based compensation paid to employees, consultants and directors, \$5.3 million of amortization of intangible assets, \$2.5 million in deferred grant income, \$1.7 million of accounts payable and accrued liabilities, \$1.1 million of depreciation expenses, \$772,000 in deferred license and subscription revenues, \$486,000 in subsidiary common shares in lieu of cash in outside research, \$245,000 of amortization of discount on convertible debt, \$168,000 in grant receivables, \$114,000 in amortization of deferred license and royalty fees and \$102,000 in amortization of deferred license and royalty revenues. This overall difference was offset to some extent by a net loss of \$11.1 million allocable to the non-controlling interest in our subsidiaries, \$4.5 million of deferred income tax benefit, \$3.7 million in gain on equity method investment, \$1.5 million of prepaid expenses and other current assets, \$248,000 of accounts receivables, and \$100,000 of other long-term assets.

Cash flows from investing activities

During the year ended December 31, 2015, \$7.4 million was used for investing activities. The primary components of this cash were approximately \$4.1 million used in leasehold improvements for Asterias' Fremont facility, \$1.2 used in the purchase of equipment, \$860,000 used to pay security deposits on new leases, \$748,000 used to purchase foreign available-for-sale securities, and advances to Hepregen of \$500,000 which were included as part of the total consideration in contribution of assets to Ascendance during December 2015.

Cash generated by financing activities

During the year ended December 31, 2015, we and our subsidiaries raised gross proceeds of \$576,000 from the sale of 175,000 BioTime common shares at a weighted average price of \$3.29 per share in "at-the-market" transactions through a broker-dealer acting as sales agent. The proceeds of the sale of BioTime shares by our subsidiaries belong to those subsidiaries.

In February 2015, Asterias raised approximately \$5.5 million in aggregate gross proceeds from the sale of 1,410,255 shares of its common stock at a price of \$3.90 per share through an underwritten public offering and a private placement.

In May 2015, OncoCyte sold 3,000,000 shares of its common stock for \$3.3 million in cash to two of its shareholders (see Note 8 to the consolidated financial statements).

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In May 2015, Asterias received \$11.7 million from the exercise of warrants to purchase 5,000,000 shares of its common stock, and May and June 2015, Asterias raised approximately \$2.8 million in gross proceeds from the sale of 239,231 shares of its common stock at a weighted average price of \$11.65 per share in “at-the-market” transactions through a broker-dealer acting as sales agent.

In September 2015, we raised \$8.6 million through the sale of 2,607,401 common shares at an offering price of \$3.29 to three of our shareholders. We used \$8.35 million of the proceeds to purchase additional shares of OncoCyte common stock. See Note 8 to the condensed consolidated financial statements.

During October 2015, we sold 6,530,612 common shares for \$20.4 million in the aggregate to certain investment funds in Israel that hold shares of companies that are included within certain stock indexes of the TASE. The \$3.13 purchase price per share was determined with reference to the closing price of BioTime common shares on the TASE on the date of sale. In addition, OncoCyte sold 246,356 BioTime common shares at the same price to one of the Israeli investment funds. Also during October 2015, we sold 1,600,000 common shares to our largest shareholder for \$5.1 million. The \$3.19 price of price per share was the closing price of the common shares on the NYSE MKT on the last trading day before we entered into the agreement for the sale of the shares.

We also received \$655,000 in cash from the exercise of employee stock options, certain warrants, and subsidiary stock options.

During 2015, Cell Cure Neurosciences received \$254,000 under a convertible debt arrangement from certain of its shareholders.

Contractual obligations

As of December 31, 2015, our contractual obligations for the next five years and thereafter were as follows (in thousands):

	Total	Principal Payments Due by Period			
		Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
Contractual Obligations ⁽¹⁾					
Operating leases ⁽²⁾	\$15,719	2,070	4,341	4,515	4,793
Capital lease ⁽³⁾	\$71	40	24	7	-

(1) This table does not include payments to key employees that could arise if they were involuntary terminated or if their employment terminated following a change in control.

(2) Includes the lease of our principal office and laboratory facilities in Alameda, California, and leases of the offices and laboratory facilities of our subsidiaries Asterias, LifeMap Sciences, and Cell Cure Neurosciences. Also includes three operating leases for lab equipment.

(3) Includes one capital lease for lab equipment.

Future capital needs

The operations of our subsidiary Asterias will continue to result in an increase in our operating expenses and losses on a consolidated basis, and will increase our need for additional capital on an ongoing basis. Asterias' research and development efforts will involve substantial expenses that will add to our losses on a consolidated basis for the near future. OncoCyte expects to incur increased operating and capital costs during 2016 as it continues work to develop its diagnostic tests and if, based on the results of its research and development efforts, it determines to establish a CLIA laboratory and commence marketing its first diagnostic test.

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As a public companies, Asterias and OncoCyte will incur costs associated with audits of their financial statements, filing annual, quarterly, and other periodic reports with the SEC, holding annual shareholder meetings, and public relations and investor relations. These costs will be in addition to those incurred by us for similar purposes.

We, Asterias, and OncoCyte will need to continue to sell BioTime common shares from time to time, and Asterias, OncoCyte, and some of our other subsidiaries may also seek to raise capital through the sale of their capital stock. We and our subsidiaries will also seek funding for our research and development programs from other sources such as research grants and other arrangements with third parties.

The amount and pace of research and development work that we and our subsidiaries can do or sponsor, and our ability to commence and complete the clinical trials that are required to develop products or, in the case of OncoCyte, diagnostic tests, and to obtain FDA and foreign regulatory approval of products, and for OncoCyte, federal and state approval of a CLIA laboratory, depend upon the amount of money we and our subsidiaries have. Future research, development, and clinical study costs are not presently determinable due to many factors, including the inherent uncertainty of these costs and the uncertainty as to timing, source, and amount of capital that will become available for our projects. OncoCyte will also need additional capital to recruit, hire, and train a sales and marketing staff as it completes development and initiates commercialization of its diagnostic tests.

Because our revenues, and those of our subsidiaries, are not presently sufficient to cover operating expenses, we and our subsidiaries will continue to need to obtain additional equity capital or debt in order to finance operations. The future availability and terms of equity or debt financing are uncertain. The unavailability or inadequacy of financing or revenues to meet future capital needs could force us and our subsidiaries to modify, curtail, delay, or suspend some or all aspects of our planned operations. Sales of additional equity securities by us or our subsidiaries could result in the dilution of the interests of present shareholders.

Off-Balance Sheet Arrangements

As of December 31, 2015, we did not have any off-balance sheet arrangements, as defined in Item 303(a) (4) (ii) of SEC Regulation S-K.

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Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Foreign Currency Exchange Risk

We are exposed to some foreign exchange currency risks because we have subsidiaries that are located in foreign countries. We do not engage in foreign currency hedging activities. Because we translate foreign currencies into United States dollars for reporting purposes, currency fluctuations have an impact on our financial results. We believe that our exposure to currency exchange fluctuation risk is mitigated by the fact that our foreign subsidiaries pay their financial obligations almost exclusively in their local currency. As of December 31, 2015, currency exchange rates did not have a material impact on our intercompany transactions with our foreign subsidiaries. However, a weakening of the dollar against the foreign exchange used in the home countries of our foreign subsidiaries could increase our cost of providing additional financing to our foreign subsidiaries in the future. Conversely, a strengthening of the dollar would decrease our cost of making additional investments in those subsidiaries.

Credit Risk

We and our subsidiaries place some cash in U.S. banks and invest most of our cash in money market funds. Deposits with banks may temporarily exceed the amount of insurance provided on such deposits. We will monitor the cash balances in the accounts and adjust the cash balances as appropriate, but if the amount of a deposit at any time exceeds the federally insured amount at a bank, the uninsured portion of the deposit could be lost, in whole or in part, if the bank were to fail. Investments in money market funds are not insured or guaranteed by the United States government or any of its agencies.

Our foreign subsidiaries deposit their cash in local banks, but if the amount of a deposit at any time exceeds the amount at a bank under the national banking insurance laws, the uninsured portion of the deposit could be lost, in whole or in part, if the bank were to fail.

Interest Rate Risk

We and our subsidiaries invest most of our cash in money market funds. The primary objective of our investments will be to preserve principal and liquidity while earning a return on our invested capital, without incurring significant risks. Our future investment income is not guaranteed and may fall short of expectations due to changes in prevailing interest rates, or we may suffer losses in principal if the net asset value of a money market fund falls below \$1 per share.

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REPORT OF INDEPENDENT PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
BioTime, Inc.

We have audited the internal control over financial reporting of BioTime, Inc. and Subsidiaries (collectively, the “Company”) as of December 31, 2015 and 2014, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying “Item 9A, Management’s Report on Internal Control Over Financial Reporting.” Our responsibility is to express an opinion on the company’s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, BioTime, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of BioTime, Inc. and Subsidiaries as of December 31, 2015, and the related consolidated statements of operations, comprehensive loss, changes in shareholders’ equity, and cash flows for the year then ended and our report dated March 15, 2016 expressed an unqualified opinion thereon.

/s/ OUM & Co. LLP
San Francisco, California
March 15, 2016

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
BioTime, Inc.

We have audited the accompanying consolidated balance sheets of BioTime, Inc. and Subsidiaries (collectively, the “Company”) as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, shareholders’ equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of BioTime, Inc. and Subsidiaries at December 31, 2015 and 2014, and the results of their operations and their cash flows for the years then ended.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), BioTime Inc. and Subsidiaries’ internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2016 expressed an unqualified opinion thereon.

/s/ OUM & CO. LLP

San Francisco, California
March 15, 2016

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
BioTime, Inc.

We have audited the accompanying consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flows of BioTime, Inc. and subsidiaries (collectively, the "Company") for the year ended December 31, 2013. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. Our audit of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall consolidated financial statement presentation. We believe that our audit provide a reasonable basis for our opinions.

In our opinion, the consolidated financial statements of BioTime, Inc. and subsidiaries referred to above present fairly, in all material respects, the results of their operations and their cash flows for the year ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

/s/ Rothstein Kass

New York, New York
March 17, 2014

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Item 8. Financial Statements and Supplementary Data

BIOTIME, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	December 31, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 42,229	\$ 29,487
Available for sale securities	753	3
Trade accounts and grants receivable, net	1,078	1,042
Inventory	1	266
Landlord receivable	567	378
Prepaid expenses and other current assets	2,609	1,229
Total current assets	47,237	32,405
Equipment, net and construction in progress	7,539	2,858
Deferred license fees	322	337
Deposits and other long-term assets	1,299	453
Equity method investment	4,671	-
Intangible assets, net	33,592	38,848
TOTAL ASSETS	\$ 94,660	\$ 74,901
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 9,377	\$ 6,803
Capital lease liability, current portion	38	58
Promissory notes, current portion	95	-
Deferred grant income	2,513	-
Deferred license and subscription revenue, current portion	439	208
Total current liabilities	12,462	7,069
LONG-TERM LIABILITIES		
Deferred tax liabilities, net	-	4,515
Deferred revenues, net of current portion	615	-
Deferred rent liabilities, net of current portion	158	97
Lease liability	4,400	378
Capital lease liability, net of current portion	26	31
Related party convertible debt, net of discount	324	60
Promissory notes, net of current portion	220	-
Other long term liabilities	8	28
Total long-term liabilities	5,751	5,109
Commitments and contingencies (Note 13)		
SHAREHOLDERS' EQUITY		
Series A convertible preferred stock, no par value, authorized 2,000 shares as of December 31, 2015 and 2014; none and 70 issued and outstanding as of December 31, 2015 and 2014, respectively	-	3,500

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Common stock, no par value, authorized 125,000 shares; issued and outstanding shares; 94,894 issued and 90,421 outstanding as of December 31, 2015 and 83,122 issued and 78,228 outstanding as of December 31, 2014	274,342		234,850
Accumulated other comprehensive (loss)/ income	(237	)	186
Accumulated deficit	(229,181	)	(182,190)
Treasury stock at cost: 4,473 and 4,894 shares at December 31, 2015 and 2014, respectively	(18,033	)	(19,890)
BioTime, Inc. shareholders' equity	26,891		36,456
Non-controlling interest	49,556		26,267
Total shareholders' equity	76,447		62,723
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 94,660		\$ 74,901

See accompanying notes to the consolidated financial statements.

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BIOTIME, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Year Ended December 31,		
	2015	2014	2013
REVENUES:			
Subscription and advertisement revenues	\$1,357	\$1,173	\$2,218
Royalties from product sales	719	398	367
Grant income	4,502	3,297	1,573
Sale of research products and services	458	376	276
Total revenues	7,036	5,244	4,434
Cost of sales	(1,107)	(837)	(793)
Gross Profit	5,929	4,407	3,641
OPERATING EXPENSES:			
Research and development	(42,604)	(37,533)	(26,609)
Acquired in-process research and development	-	-	(17,459)
General and administrative	(29,134)	(17,556)	(15,559)
Total operating expenses	(71,738)	(55,089)	(59,627)
Loss from operations	(65,809)	(50,682)	(55,986)
OTHER INCOME/(EXPENSES):			
Interest income/(expense), net	(340)	(89)	-
BioTime's share of losses in equity method investment in Ascendance	(35)	-	-
Gain on investment (Note 12)	3,694	-	-
Other income/(expense), net	(160)	(384)	(204)
Total other income/(expense), net	3,159	(473)	(204)
LOSS BEFORE INCOME TAX BENEFIT	(62,650)	(51,154)	(56,191)
Deferred income tax benefit	4,516	7,376	3,281
NET LOSS	(58,134)	(43,779)	(52,909)
Net loss attributable to non-controlling interest	11,143	7,367	9,026
NET LOSS ATTRIBUTABLE TO BIOTIME, INC.	(46,991)	(36,412)	(43,883)
Dividends on preferred shares	(415)	(87)	-
NET LOSS ATTRIBUTABLE TO BIOTIME, INC. COMMON SHAREHOLDERS	\$(47,406)	\$(36,499)	\$(43,883)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$(0.59)	\$(0.55)	\$(0.81)
WEIGHTED AVERAGE NUMBER OF COMMON STOCK OUTSTANDING:			
BASIC AND DILUTED	79,711	66,467	54,226

See accompanying notes to the consolidated financial statements.

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BIOTIME, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(IN THOUSANDS)

	Years ended December 31,		
	2015	2014	2013
NET LOSS	\$(58,134)	\$(43,778)	\$(52,910)
Other comprehensive income/(loss), net of tax:			
Change in foreign currency translation	(424)	125	119
Available for sale investments:			
Change in unrealized (loss) on available for sale securities, net of taxes	1	-	-
	-	(2)	3
COMPREHENSIVE LOSS	(58,557)	(43,655)	(52,788)
Less: Comprehensive loss attributable to non-controlling interest	(11,143)	(7,367)	(9,026)
COMPREHENSIVE LOSS ATTRIBUTABLE TO BIOTIME, INC. COMMON SHAREHOLDERS BEFORE PREFERRED STOCK DIVIDEND	(47,414)	(36,288)	(43,762)
Preferred stock dividend	(415)	(87)	-
COMPREHENSIVE LOSS ATTRIBUTABLE TO BIOTIME, INC. COMMON SHAREHOLDERS	\$(47,829) ¹	\$(36,375) ¹	\$(43,762) ¹

See accompanying notes to the consolidated financial statements.

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BIOTIME, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

(IN THOUSANDS)

	Preferred Shares		Common Shares		Treasury Shares		Contributed Capital	Accumulated Deficit	Non-controlling Interest	Accumulated Other Income	Total Shareholders' Equity
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount					
BALANCE AT JANUARY 1, 2013	-	\$-	51,183	\$ 119,821	(1,800)	\$(8,375)	\$94	\$(101,896)	\$ 14,710	\$(60)	\$ 24,294
Common shares issued as part of investment in subsidiary	-	-	9,809	38,485	(9,809)	(38,485)	-	-	-	-	-
8,000,000 Warrants issued as part of investment in subsidiary	-	-	-	18,276	-	-	-	-	-	-	18,276
Sale of common shares, net of fees paid and amortized and syndication costs	-	-	6,284	22,297	-	-	-	-	-	-	22,297
Warrants issued to outside investors	-	-	-	1,849	-	-	-	-	-	-	1,849
Common shares issued for rent	-	-	74	254	-	-	-	-	-	-	254
Common shares issued for consulting services	-	-	42	173	-	-	-	-	-	-	173
Exercise of options	-	-	20	46	-	-	-	-	-	-	46
Stock options granted for compensation	-	-	-	2,144	-	-	-	-	-	-	2,144
Stock options granted for compensation in subsidiary	-	-	-	111	-	-	-	-	790	-	901
Sale of treasury stock	-	-	-	-	911	3,826	-	-	-	-	3,826
Outside investment in subsidiary with	-	-	-	-	-	-	-	-	5,256	-	5,256

cash												
Outside												
investment in												
subsidiary with												
assets	-	-	-	-	-	-	-	-	15,733	-	15,733	
Foreign currency												
translation gain	-	-	-	-	-	-	-	-	-	119	119	
Unrealized gain												
on												
available-for-sale												
securities	-	-	-	-	-	-	-	-	-	3	3	
NET LOSS	-	-	-	-	-	-	-	(43,882)	(9,028)	-	(52,910)	
BALANCE AT												
DECEMBER 31,												
2013	-	\$-	67,412	\$203,456	(10,698)	\$(43,034)	\$94	\$(145,778)	\$27,461	\$62	\$42,262	
Sale of common												
shares, net of fees												
paid and												
amortized	-	-	14,173	43,827	-	-	-	-	-	-	43,827	
Exercise of												
options	-	-	2,060	1,192	-	-	-	-	-	-	1,192	
Shares retired as												
part of exercise of												
options	-	-	(367)	(973)	-	-	-	-	-	-	(973)	
Shares retired to												
pay for												
employee's taxes	-	-	(156)	(415)	-	-	-	-	-	-	(415)	
Tax liability on												
treasury shares												
sold by Asterias	-	-	-	(3,611)	-	-	-	-	-	-	(3,611)	
Stock options												
granted for												
compensation	-	-	-	2,409	-	-	-	-	-	-	2,409	
Stock options												
granted for												
compensation in												
subsidiaries	-	-	-	-	-	-	-	-	1,808	-	1,808	
Restricted stock												
granted for												
compensation	-	-	-	-	-	-	-	-	234	-	234	
Subsidiary												
warrants issued to												
outside investors												
as part of sale of												
treasury stock	-	-	-	-	-	-	-	-	3,184	-	3,184	
Sale of treasury												
stock	-	-	-	(11,042)	5,804	23,144	-	-	-	-	12,102	
Sale of preferred												
stock	70	\$3,500	-	-	-	-	-	-	-	-	3,500	
Dividends on												
preferred stock	-	-	-	-	-	-	(87)	-	-	-	(87)	

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Exercise of subsidiary options	-	-	-	-	-	-	-	-	8	-	8
Outside investment in subsidiary with cash	-	-	-	-	-	-	-	-	939	-	939
Foreign currency translation gain	-	-	-	-	-	-	-	-	-	125	125
Unrealized loss on available-for-sale securities	-	-	-	-	-	-	-	-	-	(2)	(2
NET LOSS	-	-	-	-	-	-	-	(36,412)	(7,367)	-	(43,779
BALANCE AT DECEMBER 31, 2014	70	\$3,500	83,122	\$234,843	(4,894)	\$(19,890)	\$7	\$(182,190)	\$26,267	\$186	\$62,723
Sale of common shares, net of fees paid and amortized	-	-	10,738	33,897	-	-	-	-	-	-	33,897
Exercise of options	-	-	155	621	-	-	-	-	-	-	621
Warrants exercised	-	-	4	19	-	-	-	-	-	-	19
Stock options granted for compensation	-	-	-	2,003	-	-	-	-	-	-	2,003
Stock options granted for compensation in subsidiaries	-	-	-	-	-	-	-	-	8,223	-	8,223
Restricted stock granted for compensation	-	-	-	-	-	-	-	-	822	-	822
Dividend in kind	-	-	-	-	-	-	-	(712)	712	-	-
Subsidiary shares retired to pay for employee's taxes	-	-	-	-	-	-	-	-	(98)	-	(98
Subsidiary warrants exercised	-	-	-	-	-	-	-	-	11,700	-	11,700
Contingently issuable subsidiary warrants	-	-	-	-	-	-	-	-	65	-	65
Sale of treasury stock	-	-	-	(496)	421	1,857	-	-	-	-	1,361
Conversion of preferred stock to common stock	(70)	\$(3,500)	875	3,500	-	-	-	-	-	-	-
	-	-	-	(45)	-	-	(7)	(363)	-	-	(415

Dividends on preferred stock											
Exercise of subsidiary options	-	-	-	-	-	-	-	-	33	-	33
Subsidiary shares issued in lieu of cash for services received	-	-	-	-	-	-	-	-			