BIOTIME INC
Form 10-K
March 16, 2017

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, 2016

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

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

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, 2016 was $165,293,000. 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 9, 2017 was 110,853,754.

Documents Incorporated by Reference

Portions of the registrant's Proxy Statement for 2017 Annual Meeting of Shareholders are incorporated by reference in Part III

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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 “BioTime”, “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 (“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.

Deconsolidation of Asterias Biotherapeutics, Inc. Effective May 13, 2016

Effective May 13, 2016, BioTime deconsolidated Asterias Biotherapeutics, Inc. (“Asterias”) financial statements and results of operations from those of BioTime under applicable generally accepted accounting principles due to the decrease in BioTime’s percentage ownership in Asterias from 57.1% to 48.7% as a result of a sale of common stock by Asterias in a public offering. Prior to that date, Asterias was a majority-owned and consolidated subsidiary of BioTime. Since May 13, 2016, BioTime has accounted for Asterias using the equity method of accounting, electing the fair value option, with all subsequent changes in fair value included in BioTime’s consolidated statements of operations in other income and expenses. Asterias’ assets and liabilities are not included in BioTime’s audited consolidated balance sheet at December 31, 2016 due to the deconsolidation. The fair value of Asterias shares owned by BioTime is shown on BioTime’s consolidated balance sheet as of December 31, 2016. BioTime’s audited consolidated statements of operations for the year ended December 31, 2016 include Asterias’ results from January 1, 2016 through May 12, 2016, the day immediately preceding the deconsolidation.

Audited financial statements of Asterias for the year ended December 31, 2016 will be included as financial statement schedules in Part IV, Item 15 by an amendment to this Form 10-K.

For further discussion see the Notes to Consolidated Financial Statements and Management’s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Report.

Deconsolidation of OncoCyte Corporation Effective February 17, 2017

Effective February 17, 2017, BioTime deconsolidated OncoCyte Corporation's ("OncoCyte") financial statements and results of operations from those of BioTime under applicable generally accepted accounting principles. This deconsolidation occurred due to the decrease in BioTime's percentage ownership in OncoCyte from 51.1% to 49.9% as a result of the issuance of 625,000 shares of OncoCyte common stock to certain investors who exercised OncoCyte warrants. Prior to that exercise, and for all the financial statement periods presented in this Annual Report, OncoCyte was a majority-owned and consolidated subsidiary of BioTime. Beginning on February 17, 2017, BioTime will no longer include the results of operations and cash flows of OncoCyte in its consolidated results and cash flows. As of February 17, 2017, BioTime plans to account for OncoCyte using the equity method of accounting by electing the fair value option. The fair value option requires BioTime to present the fair value of its interest in OncoCyte on its consolidated balance sheet, with changes in the fair value included in BioTime's consolidated statements of operations in other income and expenses. As of, and for each reporting period after February 17, 2017, the fair value of BioTime's interest in OncoCyte will be determined by the number of shares of OncoCyte held by BioTime and the closing price of the OncoCyte common stock as quoted on NYSE MKT: OCX.

For further discussion, see the Notes to Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Report.

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Item 1. Business

Overview

BioTime is a clinical-stage biotechnology company focused on developing and commercializing products addressing degenerative diseases. Our clinical programs are based on two platform technologies: pluripotent stem cells and cell/drug delivery platform technologies. The foundation of our core therapeutic technology platform is pluripotent cells that are capable of becoming any of the cell types in the human body. The foundation of our cell delivery platform is its HyStem® cell and drug delivery matrix technology. Our current clinical programs are targeting three primary sectors, aesthetics, ophthalmology and cell/drug delivery.

We also have significant equity holdings in two publicly traded companies, Asterias Biotherapeutics, Inc. ("Asterias") and OncoCyte Corporation ("OncoCyte"), which we founded and which, until recently, were our majority-owned consolidated subsidiaries. Asterias (NYSE MKT: AST) is presently focused on advancing three clinical-stage programs that have the potential to address areas of very high unmet medical need in the fields of neurology (spinal cord injury) and oncology (Acute Myeloid Leukemia and lung cancer). OncoCyte (NYSE MKT: OCX) is developing confirmatory diagnostic tests for lung cancer, breast cancer, and bladder cancer utilizing novel liquid biopsy technology. The combined market value of BioTime's holdings in Asterias and OncoCyte was about $146 million as of March 9, 2017.

BioTime, Inc. and its subsidiaries and affiliates are sometimes referred to as the "BioTime Family of Companies." BioTime is also enabling early-stage programs in new technologies through its own research programs as well as through other members of the BioTime Family of Companies. These technologies have the potential to significantly improve the treatment of diseases associated with aging, including diseases such as diabetes and cardiovascular and metabolic disorders, that affect large numbers of people. We are also researching other novel technologies that may help the body regenerate certain types of degenerated cells and tissues.

The BioTime Family of Companies currently has seven product candidates in human clinical trials, one of which is in a late-stage, pivotal study in Europe, one cancer diagnostic that is expected to be commercially launched in the U.S. later this year and several exciting early-stage programs that may help address some of the biggest unmet medical needs faced by our aging population.

Core Technology Platforms

We believe the BioTime Family of Companies has the world's premier collection of pluripotent stem cell assets and a proprietary therapeutic delivery platform with many potential uses. Pluripotent stem cells are capable of becoming any of the cell types in the human body. Cell types derived from pluripotent stem cells have potential applications in many areas of medicine with large unmet patient needs, including various tissue injuries and age-related degenerative diseases and degenerative conditions for which there presently are no cures. Unlike pharmaceuticals which almost always require a molecular target, cell therapy strategies use cell types derived from pluripotent stem cells to regenerate, replace or augment affected cells and tissues, and therefore may have broader applicability and impact than traditional pharmaceutical products. Our pluripotent stem cell technology is complemented by our HyStem® technology, which includes a family of unique, biocompatible resorbable hydrogels to deliver bioactive compositions for therapeutic benefit. HyStem® was designed to enable the effective transfer, engraftment and metabolic support for cells, whether derived from pluripotent stem cells or from a patient's own somatic or adult stem cells. The flexibility of the HyStem® technology also allows for direct therapeutic use and the sustained delivery of therapeutics.

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Clinical Therapeutic Product Candidates Being Developed By BioTime

Our near term therapeutic focus is in three core areas: Aesthetics, Ophthalmology, and Delivery

Facial Aesthetics

Renevia®, our lead facial aesthetics product, is a potential treatment for facial lipoatrophy. “Lipoatrophy” is another word for “fat loss or deficiency.” It is currently in a pivotal clinical trial in Europe to assess its safety and efficacy in restoring normal skin contours in patients whose subcutaneous fat, or adipose tissue, has been lost due to the use of certain drugs often used to treat patients with HIV. While this pivotal trial, if successful, is expected to enable a filing for marketing authorization in the European Union, BioTime sees this trial as also supportive of U.S. development of Renevia®, for the much larger market opportunity, for treating additional forms of facial volume restorations, whether from drugs, trauma or aging. Renevia® consists of our cell-transplantation delivery matrix (HyStem®) combined with the patient’s own adipose progenitor cells. Developed as a superior alternative for traditional fat transfer procedures, Renevia® is designed to mimic the naturally-occurring extracellular matrix and provide a 3-D scaffold that enables effective cell transplant, engraftment and proliferation. Renevia®, is being developed with the goal of providing a natural, long-lasting improvement to the patient’s skin contouring.

Ophthalmology

OpRegen® is our lead product for ophthalmological disorders. It is a suspension of retinal pigment epithelial (RPE) cells that are derived from pluripotent stem cells. RPE cells form the back lining of the retina, and support the function of photoreceptors (rods and cones). RPE cells can be damaged and lost in various forms of retinal degeneration. The OpRegen® therapeutic approach is to replace damaged or lost RPE cells and possibly slow disease progression and/or preserve or restore visual function. It is currently in a Phase I/IIa clinical trial for the treatment of the dry form of age-related macular degeneration (“AMD”). AMD affects approximately 1.6 million newly diagnosed people annually in the U.S and is the leading cause of blindness in people over the age of 60. Approximately 90 percent of AMD patients suffer from the dry form (“dry-AMD”), for which there are no FDA-approved therapies.

In February 2017, we expanded our ophthalmology portfolio through the acquisition of exclusive global rights to technology from University of Pittsburgh through the execution of an Exclusive License Agreement. This technology allows the generation of three-dimensional laminated human retinal tissue derived from human pluripotent stem cells. This tissue contains all the cell types and layers of the human retina and has shown evidence of functional integration in proof of concept animal models for advanced retinal degeneration. The technology is being developed for implantation in patients to potentially treat or prevent a variety of retinal degenerative diseases.

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Delivery

In addition to Renevia®, we have two additional primary programs utilizing our proprietary HyStem® technology. HyStem®-BDNF is a preclinical development program for the delivery of recombinant human brain-derived neurotrophic factor (BDNF) directly into the stroke cavity of patients with the goal of aiding in tissue repair and functional recovery. ReGlyde™ is in preclinical development as a device for viscosupplementation and a combination product for drug delivery in osteoarthritis (OA). The viscosupplementation device program aims to administer ReGlyde™ directly into OA affected joints provide joint lubrication to reduce pain and improve quality of life. The drug delivery programs seek to enable the sustained release of therapeutics in affected OA joints to slow or reverse disease progression, in addition to improving pain and joint function. Also, included in our delivery platform is Premvia™, which is a HyStem® hydrogel formulation for the management of wounds including partial and full-thickness wounds, ulcers, tunneled/undermined wounds, surgical wounds, and burns. Premvia™ was cleared by the FDA via a 510(k) device approval pathway.

In addition to these programs, BioTime is developing HyStem® product enhancements. Current efforts are focused on the development of a frozen liquid product format, which, if successful, will make significant improvements in end-user convenience.

Products for Orthopedic Indications

We have a regenerative medicine orthopedic program that is a collaboration between our subsidiary OrthoCyte Corporation (“OrthoCyte”), and Heraeus Medical GmbH. The companies are developing innovative bone grafting therapies to address difficult to heal and/or compromised bone fractures based on the use of our proprietary PureStem® human embryonic progenitor cell (“hEPC”) technology.

Product Candidates of Public Affiliates

BioTime has retained a significant, non-strategic equity interest in two public companies that were founded by BioTime, Asterias, and OncoCyte are focused on neurology, oncology and diagnostics. As of March 9, 2017, the combined value of these holdings was approximately $146 million.

Therapeutic Products in Neurology and Oncology

Asterias is presently focused on advancing three clinical-stage programs, which have the potential to address areas of very high unmet medical need in the fields of neurology and oncology. Asterias’ lead products are:

- AST-OPC1 is a therapy derived from pluripotent stem cells that is currently in a Phase I/IIa clinical trial for spinal cord injuries, with positive early efficacy data reported in September 2016.

- AST-VAC1 is a patient-specific cancer immunotherapy with promising Phase II clinical trial data in acute myeloid leukemia (“AML”).

- AST-VAC2 is a non-patient specific cancer immunotherapy for which the initiation of a Phase I/IIa clinical trial in non-small cell lung cancer is planned for the first half of 2017.

Liquid Biopsies for Diagnosis of Cancer

Our affiliate OncoCyte is developing confirmatory diagnostic tests for lung cancer, breast cancer, and bladder cancer utilizing novel liquid biopsy technology. While current biopsy tests use invasive surgical procedures to provide tissue

samples to determine if a tumor is benign or malignant, OncoCyte is developing a next generation of diagnostic tests that will be based on liquid biopsies using blood or urine samples.

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OncoCyte recently conducted a 300-patient study of its lung cancer test. On March 6, 2017 OncoCyte announced the successful completion of the study.

Early-Stage and Other Research and Development

We are also developing technology related to an exciting area of regenerative medicine relevant to diseases of aging. This technology, known as “induced Tissue Regeneration” or “iTR,” may provide a new means of treating diseases caused by the degeneration of tissues. In 2016, our Co-Chief Executive Officer, Dr. Michael West, Ph.D., presented data generated from iTR. We are also developing technologies related to metabolic disorders based on the properties of brown fat, and therapies for vascular diseases, defects, and disorders. We also have several other early stage programs including our PureStem® cell therapy assets.

As part of our simplification strategy, we are looking at ways to attempt to unlock potential shareholder value associated with our early stage programs and the unique skills of Dr. West. One option under consideration is the consolidation of these early stage assets under the leadership of Dr. West.

We are also exploring other ways to fund these early stage opportunities that is consistent with our focus on clinical progress.

Strategy

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

Clinical Progress

Our efforts are focused on progressing our therapeutic products through clinical development. Our organizational capabilities are being aligned to execute on this objective to better position us to design, execute and oversee trials, with the goal of generating significant value-creating data in the near-term, and enabling future commercialization. Clinical progress success will allow the company to create greater value for investors, as well as allow us to better resource several other programs that are based on our core technologies.

Simplification

We will continue to work on simplifying our corporate, financial and organizational structure to allow us to execute our objectives more efficiently, while also making it much easier for investors, and other external stakeholders, to better understand our company.

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Unlocking value

Our purpose is to deliver therapies for significant unmet, or under-met, needs to patients, while creating value for our investors. We believe that we have several valuable assets within the BioTime Family of Companies. We have been successful in unlocking the value of these assets through the execution of various strategies, including partnering, or sale, of non-core assets, creation of companies, spin-outs, distributions, simplification actions and other tactics we may develop.

2016 Highlights

The BioTime Family of Companies achieved numerous strategic accomplishments during 2016, including advancing clinical trials and product development in several key programs.

Clinical Progress

We presented positive early Renevia® data at the International Federation for Adipose Therapeutics and Science meeting (IFATS) meeting in November. The data related to the treatment of the initial 9 run-in patients for BioTime's ongoing pivotal clinical trial in Europe assessing the efficacy of Renevia® for the treatment of HIV-associated lipoatrophy. In December, we achieved the recruitment milestone of 50 patients enrolled in the trial. We plan to stop enrollment in the trial in the first half of 2017 and to file for EU CE marking in the second half of 2017.

We presented positive early OpRegen® data at the International Symposium on Ocular Pharmacology and Therapeutics (ISOPT) in December. The data from the first cohort in the Phase I/IIa clinical trial of OpRegen® in the advanced form of dry age-related macular degeneration (dry-AMD). By end of year 2017, some 1-year follow-up of cohort 2 and data from cohort 3 and beginning enrollment of cohort 4 are expected to be completed. OpRegen® has received Fast Track designation from the FDA.

- Initial feasibility of our next-generation retinal restoration technology demonstrates engraftment of laboratory grown three-dimensional laminated human retinal tissue and functional recovery of blind rats, which was described in three presentations at the annual meeting of the Society for Neuroscience in November 2016 in San Diego by Dr. Igor Nasonkin, lab head at BioTime and at a presentation at the ISSCR congress in Basel Switzerland in February 2017.

In November 2016, Asterias successfully administered the highest dose of 20 million cells of AST-OPC1 to a patient with complete cervical spinal cord injury (SCI) as part of the SCiStar Phase I/IIa clinical trial. In January 2017, Asterias announced positive efficacy results that showed additional motor function improvement at 6-months and 9-months following administration of 10 million AST-OPC1 cells in 6 AIS-A patients with complete cervical SCI. The results suggest that the improvements in arm, hand and finger function observed earlier in the study have been maintained and even further enhanced over time in most patients. Twelve-month efficacy and safety data for this cohort, as well as 6-month efficacy and safety data for the currently-enrolling AIS-A 20 million cell and AIS-B 10 million cell cohorts are expected during the third quarter of 2017. Asterias also plans to initiate discussions with the FDA in mid-2017 to determine the most appropriate clinical and regulatory path forward for AST-OPC1.

On March 6, 2017, in relation to its blood-based diagnostic test designed to aid physicians in the early detection of lung cancer, OncoCyte announced the successful completion of a study of 300 blood samples from patients with lung nodules that had been determined to be malignant or benign, and that it has locked the prediction algorithm of the test. Based on the study results, OncoCyte announced that it will begin ramping-up its commercial capabilities in anticipation of the potential commercial launch of the test. OncoCyte will initiate a clinical validation phase for the diagnostic. During this phase, OncoCyte will also continue to carry out analytical validation studies to refine its operational stage laboratory processes, and will apply for certification of its CLIA diagnostic testing lab. Upon CLIA certification, OncoCyte will conduct a small CLIA lab validation study to demonstrate that the full assay system

utilized in the CLIA lab provides the same results on clinical samples as those obtained in the R&D lab. OncoCyte will then begin a clinical validation study on a new set of at least 300 blinded prospectively collected blood samples to confirm whether the sensitivity and specificity of the test remain within commercial parameters in a CLIA operational setting. Assuming successful completion of these steps, OncoCyte anticipates launching the test commercially in the second half of 2017.

- OncoCyte presented data from an early study of the OncoCyte's breast cancer test in a poster session at the 2016 San Antonio Breast Cancer Symposium (SABCS) in December. In January 2017, OncoCyte announced commencement of a 300-patient study for their breast cancer diagnostic test which is designed to replicate the successful findings from the earlier study. OncoCyte expects to complete this 300-patient study during mid-2017.

Simplification

- In May 2016, Asterias' financial statements were deconsolidated from BioTime's consolidated financial statements. The deconsolidation was a result of Asterias' successful completion of an equity financing, which brought our ownership in Asterias to below 50%. Although our financial statements no longer include Asterias' assets, liabilities or financial results, the value and changes in value of our shares of Asterias common stock will be reflected in our financial statements, which we believe will simplify our financial statements and may help investors better understand the financial performance and condition of BioTime's operations. GAAP requires the consolidation of 100% of a majority-owned subsidiaries' financials and results of operations even if the parent owns only a little over 50%.

- Similarly, as a result of the exercise of certain OncoCyte warrants held by certain OncoCyte investors, in February of 2017 OncoCyte's financials were deconsolidated from BioTime's consolidated financial statements. This deconsolidation is not reflected in this Report, but was reported in a Form 8-K that was filed on February 21, 2017, and will be reflected in BioTime's future quarterly and annual consolidated financial statements to be filed with the Securities and Exchange Commission (the "SEC").

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Unlocking Value

- On January 4, 2016, OncoCyte shares were listed and began trading "regular way" on the NYSE MKT under the symbol OCX. This event triggered enhanced liquidity for BioTime shareholders who received one share of OncoCyte for every 20 shares of BioTime as a dividend at the end of 2015.

Patent Portfolio

During 2016, the BioTime Family of Companies collectively had 44 new patents issued worldwide.

Non-dilutive Funding

In 2016, our subsidiary, Cell Cure Neurosciences Ltd. ("Cell Cure"), was awarded a grant of 8.4 million shekels (approximately $2.2 million) from the Israel Innovation Authority, or the IIA (formerly the Office of the Chief Scientist of Israel) of the Ministry of Economy and Industry to help finance the development of OpRegen®. This brings the total grants received to date to approximately $9 million.

Other Company News

- In June 2016, we raised $20.1 million gross proceeds from new and previous investors in an underwritten public offering of our common shares.

The BioTime Family of Companies (Affiliates & Subsidiary Ownership)

The following table shows the operating companies within the BioTime Family of Companies, their respective principal fields of business, our percentage ownership, directly and through subsidiaries, as of December 31, 2016, and the country where their principal business is located:

Subsidiaries and Affiliates	Field of Business	BioTime Ownership	Country
Cell Cure Neurosciences Ltd.	Products to treat age-related macular degeneration	62.5%(1)	Israel
ES Cell International Pte. Ltd.	Stem cell products for research, including clinical grade cell lines produced under cGMP	100%	Singapore
LifeMap Sciences, Inc.	Biomedical, gene, disease, and stem cell databases and tools	77.9%	USA
OncoCyte Corporation (2)	Cancer diagnostics	51.1%	USA
OrthoCyte Corporation	Developing bone grafting products for orthopedic diseases and injuries	100%	USA
ReCyte Therapeutics, Inc.	Research and development involved in 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
Asterias Biotherapeutics, Inc.(3)	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	46%	USA

(1) Includes shares owned by BioTime and ES Cell International Pte. Ltd. Does not include shares that would be owned by BioTime, if BioTime were to convert certain convertible debt into Cell Cure ordinary shares (see below for an explanation).

(2) See Note 16 to our consolidated financial statements included elsewhere in this Report. Beginning February 17, 2017, BioTime deconsolidated OncoCyte and OncoCyte is no longer a subsidiary of BioTime as of that date, but remains an affiliate and significant investee of BioTime.

(3) Since the deconsolidation of Asterias in May 2016, Asterias is a significant affiliate of BioTime.

Our Ownership of Cell Cure

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. We also hold certain Cell Cure convertible promissory notes that entitle us to acquire additional Cell Cure ordinary shares by converting those notes into ordinary shares. If we were to convert the convertible promissory notes into Cell Cure ordinary shares, and if no other ordinary shares are issued to third parties, our percentage ownership of Cell Cure would increase to 82.3%, based on the number of ordinary shares outstanding on February 28, 2017. Cell Cure has adopted stock option plans under which it may issue up to 125,363 of its ordinary shares to officers, directors, employees, and consultants. As of December 31, 2016, options to purchase 80,986 ordinary shares of common stock had been granted.

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We and ESI entered into a Third Amended and Restated Shareholders Agreement with Cell Cure and its other principal shareholders Teva Pharmaceutical Industries, Ltd., ("Teva") and Hadasit Bio-Holdings Ltd ("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 may issue. Under the agreement, the shareholders also granted each other a right of first refusal to purchase any Cell Cure shares that they may determine to sell or otherwise transfer in the future. The number of members on the Cell Cure board of directors is set at seven, of which we are entitled to elect four directors, HBL is entitled to elect two directors, and Teva is entitled to elect one director. These provisions were also included in an amendment to Cell Cure's Articles of Association.

To date, Cell Cure has received grants totaling approximately $9 million from the IIA for the development of OpRegen®. Under the terms of the grant agreement between Cell Cure and IIA, Cell Cure will be required to pay royalties on future product sales, if any, up to the amounts received from the IIA, plus interest indexed to LIBOR. Israeli law pertaining to such government grants contain various conditions, including substantial penalties and restrictions on the transfer of intellectual property, or the manufacture, or both, of products developed under the grant outside of Israel, as defined by the IIA.

Our Ownership of Asterias

As of March 9, 2017, we owned 44.5% 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, 2016, Asterias had outstanding warrants to purchase 6,552,479 shares of Asterias common stock, options to purchase a total of 6,065,938 shares of Asterias common stock and 52,509 restricted stock units.

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 9, 2017, we owned 49.98% 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. As of December 31, 2016, options to purchase 3,017,087 shares of OncoCyte common stock had been granted.

Our Ownership of OrthoCyte

As of March 9, 2017, we owned 99.99% 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, 2016, options to purchase 1,300,000 shares of OrthoCyte common stock had been granted.

Our Ownership of ReCyte Therapeutics

As of March 9, 2017, we owned 94.8% of the ReCyte Therapeutics common stock outstanding. Two private investors and a foundation own the other shares of ReCyte Therapeutics common stock outstanding. 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, 2016, options to purchase 1,250,000 shares of ReCyte Therapeutics common stock had been granted.

Our Ownership of LifeMap Sciences

As of March 9, 2017, we owned 77.9% of the LifeMap Sciences, Inc. (“LifeMap Sciences”) common stock outstanding. Certain current and former officers and directors of LifeMap Sciences and other investors own the other shares of LifeMap Sciences common stock outstanding. 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, 2016, options to purchase 1,596,123 shares of LifeMap Sciences common stock had been granted.

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Additional Information

BioTime is 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. OpRegen® is a registered trademark of Cell Cure. GeneCards® is a registered trademark of Yeda Research and Development Co. Ltd. LifeMap Discovery® is a registered trademark of LifeMap Sciences.

In 2016, BioTime was led by the Co-CEO leadership team of Adi Mohanty, who is responsible for human clinical development, product commercialization, corporate and administrative functions and Dr. Michael D. West, one of the world's foremost experts on therapies derived from stem cells, who is responsible for research, product discovery, and preclinical product development.

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 in advancing various programs and product lines through development. However, the operation of our business through multiple subsidiaries and affiliated companies results in certain administrative expenses that we would not incur if all our operations were conducted within BioTime itself. Because of this organizational structure which has facilitated our fundraising efforts, the BioTime Family of Companies has developed multiple clinical-stage products, rather than being dependent on a single product program. We, and some of the other members of the BioTime Family of Companies, 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.

Technology Platforms

Pluripotent Cell Technology:

BioTime believes that it and its subsidiaries and affiliates have the world's premier collection of pluripotent cell assets. Pluripotent cells, which are capable of becoming any of the cell types of the human body, have potential applications in many areas of medicine with large unmet patient needs, including various age-related degenerative diseases and degenerative conditions for which there are presently no cures. Unlike pharmaceuticals that require a molecular target, therapeutic strategies based on the use of pluripotent cells are generally aimed at regenerating or replacing affected cells and tissues, and therefore may have broader applicability than pharmaceutical products.

BioTime has two key pluripotent platforms, PureStem® and ESI pluripotent stem cell lines. PureStem® human Embryonic derived Progenitor Cells (hEPC) address significant challenges in regenerative medicine through their purity, proliferative capacity and ability to better predictably acquire tissue specificity or "differentiate," into a broad spectrum of cell types in a simplified and controlled fashion. These advantages allow the production, on a commercial scale, of pure cultures of potentially therapeutic cell types that do not contain uncharacterized "undifferentiated" cell types. The ESI pluripotent stem cell lines are the first clinical grade human embryonic stem cell

lines and they were derived under current Good Tissue Practice (cGTP) conditions. They are NIH-registered and are among the best-characterized and documented human stem cell lines available today, with complete genome sequence, STR-fingerprint and HLA-type data available.

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HyStem® Delivery Technology:

HyStem® is a patented biomaterial that mimics the extracellular matrix ("ECM"), the structural 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 accurate anatomical delivery, cell retention and engraftment, guided tissue remodeling and 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 cells and tissue types including brain, bone, skin, cartilage, and vascular and heart tissues.

The patented technology underlying our HyStem® hydrogel products in development, such as Renevia® and ReGlyde™, was developed at the University of Utah and has been exclusively licensed to us for human therapeutic uses. The HyStem® technology is based on a unique thiol cross-linking chemistry 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.

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 combining bioactive materials with the hydrogel at the point of use. Building upon this platform, we are developing the HyStem® family of unique, biocompatible resorbable hydrogel products.

Therapeutic Product Candidates Being Developed By BioTime

Facial Aesthetics
Renevia®

We are developing Renevia®, a clinical-grade HyStem® hydrogel, as an injectable product. Renevia® is being developed to address an immediate need in facial aesthetic procedures, and certain reconstructive surgeries, by improving the process of transplanting a patient's own fat progenitor cells to potentially provide a better looking, more natural feeling and longer lasting benefit.

Cells obtained from a patient, such as adipose cells obtained through liposuction, can be transplanted back into the same patient at another location in the body without the risk of rejection and potential contamination associated with the transplant of allogenic 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 attach and rebuild normal tissue.

We are conducting a multi-site pivotal clinical study in Spain to assess the efficacy of Renevia® as a delivery matrix for fat progenitor cells to restore normal skin volume 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 most frequently a consequence of the normal aging process, but lipoatrophy can also be associated with trauma, surgery, drug side effects and diseases. Lipoatrophy is frequently experienced by HIV patients who have been treated with certain anti-retroviral 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.

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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. Patients are being monitored at one, three, and six-month intervals after treatment.

Data from the run-in portion of the study (N=9) indicated that adipose progenitor cells (fat cells), obtained from a liposuction aspirate, remained viable and were observed to proliferate when combined with Renevia® hydrogel. Analysis suggests that the grafts retain volume over the assessment period, and the treating physician observed incremental volume was retained in patients who had progressed to the one-year follow-up evaluation. In addition, there were encouraging signs of new tissue regeneration observed. No serious adverse events were noted during the run-in portion of the study.

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 complete the pivotal trial during the first half of 2017 and file for EU CE marking at the end of 2017. While this pivotal trial will enable a European filing for marketing authorization, we plan to use this trial to support US development of Renevia® for multiple forms of facial lipoatrophy, whether from drugs, trauma or aging. Once we analyze the data for the study, we plan to continue our discussion with the FDA regarding a potential development plan for Renevia® in the U.S.

Ophthalmology

OpRegen®

Our lead ophthalmology product, OpRegen®, is derived from pluripotent cell technology. It is currently in a Phase I/IIa clinical trial for the treatment of the dry form of age-related macular degeneration (“AMD”). Cell Cure, which is BioTime’s subsidiary in Israel, is conducting the current clinical trial. OpRegen® is a proprietary formulation of retinal pigmented epithelial (“RPE”) cells developed to be transplanted into the patient’s eye, where the patient’s own RPE cells are missing. OpRegen® consists of animal product-free RPE cells with high purity and potency using a proprietary directed differentiated method. OpRegen® is formulated as a suspension of RPE cells. It was developed to address the high, unmet medical needs of people suffering from dry aged-related macular degeneration.

AMD affects approximately 1.6 million newly diagnosed people annually in the U.S and is the leading cause of blindness in people over the age of 60. Approximately 90 percent of AMD patients suffer from the dry form (“dry-AMD”), for which there are no FDA-approved therapies.

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AMD is a major disease 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.

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. The primary objective of this trial is to evaluate the safety of three different dose regimens in the treatment of the advanced form of dry age-related macular degeneration (dry-AMD), a condition for which there is currently no FDA-approved therapy. The study will evaluate three different dose regimens of OpRegen® in four cohorts.

All patients enrolled in the study 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®. Currently there are three study sites in Israel and two sites in the initiation process in the U.S. Enrollment in the second cohort, in which patients are receiving a higher and more clinically meaningful 200,000 cell dose started in 2016. Cell Cure intends to approach the DSMB in the second quarter of this year for approval to begin administering the next higher, 500,000 cell dose to the third cohort, and if approved, also begin the fourth cohort before year end. The most up-to-date data from patients in cohort 2 of the clinical trial will be presented May 7-11 at ARVO 2017 in Baltimore, Maryland.

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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 will be to examine the ability of transplanted OpRegen® to engraft, survive, and modulate disease progression in the patients. In addition to thorough characterization of visual function, a battery of vision tests will be used to quantify improvements in reducing the progression of the disease. Research and development of the enabling technology of OpRegen® has been conducted at Hadassah Medical Organization ("Hadassah"), and the clinical development is being conducted by Cell Cure under an exclusive license from Hadasit Medical Research Services and Development Limited ("Hadasit"), which is the technology transfer office of Hadassah.

Data from the first cohort of patients were presented at the International Symposium on Ocular Pharmacology and Therapeutics (ISOPT) on Friday, December 2, 2016, in Rome, Italy. In this cohort, OpRegen® was successfully administered with no serious adverse events. Retinal imaging presented suggested the presence and survival of the transplanted cells in the sub-retinal space for up to one year.

Retinal Restoration

In February 2017, we acquired exclusive global rights to ophthalmology-related intellectual property assets from the University of Pittsburgh. The technology was developed, in part, in collaboration with BioTime scientists, and includes composition and methodologies to develop 3-D retinal tissue constructs from pluripotent stem cells for implantation in patients with advanced stages of retinal degeneration.

This technology will allow generation of three-dimensional laminated human retinal tissue in a controlled manufacturing process. This could lead to retinal restoration treatments for a variety of advanced retinal degenerative diseases, such as retinitis pigmentosa, macular degeneration, and diabetic retinopathy.

Delivery

HyStem®-BDNF

HyStem®-BDNF is a hydrogel-BDNF combination product made of our HyStem® delivery system with rhBDNF is in preclinical development for ischemic stroke. HyStem®-BDNF permits sustained local diffusion of BDNF into the peri-infarct tissue, currently in preclinical development for ischemic stroke. HyStem®-BDNF involves a proprietary formulation of the HyStem® hydrogel platform allowing a sustained release of BDNF, which is being developed to maximize tissue repair and recovery after neurological insult. Pre-clinical results indicate that when treating animals with focal stroke to motor areas of the brain, HyStem®-BDNF intra-stroke cavity injection results in BDNF diffusion from the stroke cavity into peri-infarct tissue over three weeks compared with one week for BDNF-only injection. The sustained release of BDNF in these animals is associated with improved post-stroke neurogenesis in the peri-infarct cortex, axonal sprouting in the motor system, and behavioral motor recovery.

ReGlyde™

ReGlyde™ is a proprietary formulation of the HyStem® hydrogel platform and is currently in preclinical development for viscosupplementation and drug delivery in osteoarthritis. Pre-clinical results are encouraging and have shown biocompatibility and preclinical efficacy signals in animal models.

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Research and Development and License Agreements with Heraeus Medical GmbH

BioTime is developing cellular therapeutics for orthopedic disorders. During September 2015, we, through our subsidiary, 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, BioTime is responsible for research and development of a cell therapy bone grafting product using PureStem® technology and either HyStem® scaffold technology for delivery of bio-active components or scaffold technology owned by Heraeus or licensed to Heraeus from third parties.

BioTime is presently diligently developing bone grafting products for the Heraeus sponsored program. If sufficient funding becomes available, we may also 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, and 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 BioTime to impact the disease process is an important differentiating factor from other competing technologies.

Product Candidates of Public Affiliates

Therapeutic Products in Neurology and Oncology

Asterias is presently focused on advancing three clinical-stage programs which have the potential to address areas of very high unmet medical need in the fields of neurology and oncology.

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

AST-OPC1 is comprised of oligodendrocyte progenitor cells, which are cells that become oligodendrocytes after injection. It has been shown preclinically to have three potentially reparative functions that address the complex pathologies observed at the injury site of a spinal cord injury. These activities of AST-OPC1 include production of neurotrophic factors, stimulation of vascularization, and induction of remyelination of denuded axons, all of which are critical for survival, regrowth and conduction of nerve impulses through axons at the injury site.

AST-OPC1 was tested in patients with acute SCI in a Phase I and a Phase I/IIa dose escalation ("SCIStar study") trials that were initiated in October 2010 and March 2015, respectively. In January 2017, Asterias announced additional interim efficacy data from the SCIStar study on the patients who were enrolled and dosed in the AIS-A 10 million-cell cohort, which included the following observations:

Improvements in Motor Function

· Upper Extremity Motor Score - For the five patients who had completed at least 6 months of follow-up at the time of the announcement, five of five patients saw their early improvements in upper extremity motor score (UEMS) at 3 months maintained or further increased through their most recent data point (6 months or 9 months, depending on the

most recent data available for each patient).

- Motor Level Improvement - For patients completing at least 6 months of follow up, as of the date of each patient's last follow-up visit, 100% (five of five) had achieved at least a one motor level improvement (using the ISNCSCI scale) over baseline on at least one side, and 40% (two of five) had achieved two motor levels over baseline on at least one side, with one of these patients achieving a two-motor level improvement on both sides.

Safety

- The trial results from the Phase I/IIa study continued to reveal a positive safety profile for AST-OPC1. There have been no serious adverse events related to AST-OPC1 and data from the study indicate that AST-OPC1 can be safely administered to patients in the subacute period after severe cervical spinal cord injury.

Asterias expects to complete enrollment of its Phase I/IIa study in the second half of 2017, with interim updates occurring at various times in 2017 and 2018.

There are approximately 17,000 new spinal cord injuries annually (NSCIC SCI Facts and Figures at a Glance (2016)). There are currently no drugs approved by the United States Food and Drug Administration ("FDA") specifically for the treatment of spinal cord injury.

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

AST-VAC1: Autologous Telomerase-loaded Dendritic Cells

AST-VAC1 is an Asterias' 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. A Phase II clinical trial of AST-VAC1 was conducted and demonstrated that AST-VAC1 was successfully manufactured and released in 24 out of the 33 patients enrolled in the study. 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. 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 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.

The next major step in clinical development for AST-VAC1 would be to conduct a confirmatory Phase 2b study in higher risk patients over 60 years old.

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 human embryonic stem ("hES') cells that can be modified with any antigen. In 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. The Asterias technology transfer to CRUK has been completed and patient enrollment for this study is expected to begin in the second half of 2017.

Liquid Biopsies for Cancer Diagnostics

OncoCyte is developing diagnostic tests for lung cancer, breast cancer, and bladder cancer utilizing novel liquid biopsy technology. While current biopsy tests use invasive surgical procedures to provide tissue samples to determine if a tumor is benign or malignant, OncoCyte is developing highly accurate, easy to administer, non-invasive molecular diagnostic tests that will be based on liquid biopsies using blood or urine samples.

Clinical Trials-Lung Cancer Diagnostic

OncoCyte collaborated with the Wistar Institute of Anatomy and Biology ("Wistar") to develop one of the components of the confirmatory lung cancer diagnostic test in a large, multi-site clinical study. This collaboration involved a clinical study with over 2,000 blood samples obtained from patients with a high-risk profile for development of lung cancer, which led to the discovery of biomarkers that differentially express in lung cancer patients.

Confirmatory diagnostics are used in conjunction with a current standard of care screening procedure. A lung confirmatory diagnostic would be used in conjunction with Low Dose CAT Scan (LDCT) to confirm a suspicious nodule by yielding a secondary suspicious versus benign result. In the case of a benign result, the patient would not need additional invasive procedures to determine the presence of cancer. In the case of a suspicious result, additional procedures would be highly warranted.

In October of 2016, Wistar presented a larger proof of concept study at the Chest annual meeting, where it validated the results of the ATS study with comparable findings. In this larger analysis of 610 patients, showing that the biomarkers alone had an Area Under the Curve (“AUC” or “ROC score”) of 0.82, resulting in a sensitivity of 90% and a specificity of 62%. These results suggest that a diagnostic comprised of biomarkers and a classifier could help clinicians manage the intermediate size nodules in way that would both improve health outcomes by potentially avoiding morbidity and mortality associated with lung biopsies, as well as decreasing the overall costs of lung cancer detection.

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To provide independent validation of Wistar's work, OncoCyte elected to develop its own assay system and algorithm using the biomarkers identified by Wistar. OncoCyte collected its own clinical samples from 300 patients over 26 sites nationwide. The study was designed to provide a set of samples that were geographically diverse, from different types of care centers, and representing a cross-section of the high-risk patient population with nodules.

On March 6, 2017, OncoCyte announced the successful completion of the study and that it has locked the prediction algorithm of the test. Based on the study results, OncoCyte announced that it will begin ramping-up its commercial capabilities in anticipation of the potential commercial launch of the test. OncoCyte will initiate a clinical validation phase for the diagnostic. During this phase, OncoCyte will also continue to carry out analytical validation studies to refine its operational stage laboratory processes, and will apply for certification of its CLIA diagnostic testing lab. Upon CLIA certification, OncoCyte will conduct a small CLIA lab validation study to demonstrate that the full assay system utilized in the CLIA lab provides the same results on clinical samples as those obtained in the R&D lab. OncoCyte will then begin a clinical validation study on a new set of at least 300 blinded prospectively collected blood samples to confirm whether the sensitivity and specificity of the test remain within commercial parameters in a CLIA operational setting. Assuming successful completion of these steps, OncoCyte anticipates launching the test commercially in the second half of 2017.

Clinical Trials—Breast Cancer Diagnostic

OncoCyte completed a strong proof of concept study for its breast cancer confirmatory test, and presented data at the San Antonio Breast Cancer Symposium (SABCS) in December of 2016. The study looked at serum from 100 women who had a mammogram with a result of BIRADs 3 or 4. The results of this analysis were promising, with a 15-marker model producing a sensitivity of 90% and a specificity of 76%.

OncoCyte is continuing development of a breast cancer confirmatory diagnostic by conducting a larger study that it expects will analyze blood samples from approximately 300 patients with benign or malignant nodules.

Clinical Trials—Bladder Cancer Diagnostic

As part of the clinical development of a urine-based bladder cancer diagnostic test, OncoCyte initiated a clinical trial in January 2014 and in May of 2015, they presented preliminary findings of their bladder research, which showed a sensitivity of 90% and a specificity of 83%. Sensitivity is the probability of detecting the presence of the disease accurately. 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 has decided to pursue a co-development partner for its bladder cancer test.

Early-Stage and Other Research and Development

Treatment of Vascular Disorders

We are using vascular cells derived from pluripotent stem cells, and other technologies, to develop treatments for vascular disorders. The therapeutic indications we are targeting 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 consumes a major and ever-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. We are conducting this research through our subsidiary, ReCyte Therapeutics.

During August 2011, we 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. We are using the Cornell technology in combination with the PureStem® technology to produce highly purified monoclonal embryonic vascular endothelial progenitor stem cells.

Brown Fat Technology for Treatment of Metabolic Disorders

Brown adipose tissue (BAT) cells, or as they are sometimes called “brown fat cells,” have only recently become the subject of intense study by medical researchers. Unlike normal white adipose tissue (WAT) which is the fat we normally associate with obesity and disorders correlated with obesity such as Type II Diabetes (T2D), BAT cells don’t simply store calories. BAT cells burn calories in the process of generating body heat. In addition, the cells secrete biological active molecules that are believed to play an important role in maintaining the body in a state of metabolic health. Recently it has also been reported that humans lose BAT as a function of age and the loss of these cells are implicated in unhealthy age-related changes in metabolism such as obesity, T2D, and metabolic syndrome. This recent discovery may have important consequences for regenerative medicine, since pluripotent cells provide a means of manufacturing all human cell types on an industrial scale, including BAT cells. Our research team has invented a technology to manufacture BAT cells and filed certain patent applications that it believes provides it with a path to develop BAT cells for the potentially large and growing markets associated with obesity and T2D. Prior to initiating human clinical trials, we will be required to successfully perform extensive preclinical testing of the cells to determine their safety and efficacy in non-human model systems.

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iTR

When tissues in the human body are damaged as a result of degenerative disease, injury, or surgery, there is generally a very limited capacity of the body to regenerate the tissue back to its original state. Exceptions to this rule is blood and the liver, both of which both show a remarkable capacity to restore equilibrium after the loss of cells. Other exceptions are tissues in the human body when it is first being formed. Early in development tissues such as the skin can repair itself scarlessly, but this ability is lost even before we are born. Another example in the animal kingdom is the Mexican salamander which shows a profound capacity to regenerate damaged tissues, even restoring severed limbs. However, in the adult human, most tissues simply scar rather than regenerate. Our scientists have been performing certain research to understand the molecular mechanisms regulating this loss of regenerative potential after the human body is formed based on its expertise in pluripotent stem cell technology. As a result, these scientists have invented a novel technology we call “induced Tissue Regeneration” or “iTR.” iTR is designed to eventually facilitate the identification of therapies to induce scarless regeneration of tissues in the body that currently cannot naturally repair themselves. Examples of potential applications are numerous, but we are particularly focused currently on the regeneration of the heart following infection or heart failure, and scarless skin regeneration. iTR is a revolutionary new approach to medicine and as a result, the program will require us to communicate the science effectively to the scientific community and perform preclinical studies to demonstrate its safety and efficacy prior to any human clinical trials.

Databases and Tools for Biomedical, Gene, Stem Cell, and Disease Research

LifeMap Sciences is a life sciences technology company that offers biomedical knowledgebases and NGS data analysis & interpretation solutions. Its integrated knowledgebase, the GeneCards® Suite, includes GeneCards®, the leading human gene database, LifeMap Discovery® the database of embryonic development, stem cell research and regenerative medicine; and MalaCards™, the human disease database. Its NGS data analysis and interpretation tools includes TGex, a Next Generation Sequencing (NGS) cloud-based solution for interpretation, 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.

Licensed Technology and Product Development Agreements

BioTime and other members of the BioTime Family of Companies 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.

We will pay WARF a 4% royalty on the sale of research products and services and 2% on the sale of related products under the WARF license. The royalty rate is subject to certain reductions if we also become obligated to pay royalties to a third party to sell a product. We have certain options to negotiate with WARF to obtain a license to manufacture and market therapeutic products, excluding products in certain fields of use. The WARF license shall remain in effect until the last licensed patent expires, however, we may terminate prior to the expiration by giving WARF at least 90 days written notice, and WARF has industry standard termination rights.

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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.

We have 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 we also have 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 latest expiration date of patents issued is October 12, 2026, but the expiration date of the licenses could be extended if the patent expiration dates are extended. 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 to Ocata through the effective date of the termination.

HyStem® Hydrogel Technology

We have acquired an exclusive worldwide license from the University of Utah to use certain patents in the production and sale of hydrogel products, including our HyStem® products, excluding certain veterinary and animal heath uses. 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.

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 of Utah, 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.

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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, and will reimburse OrthoCyte for all costs and expenses incurred in connection with the project. 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. Heraeus had additional industry standard termination rights. OrthoCyte has also 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, and termination provisions.

Hadasit Research and License Agreement

Cell Cure 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 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 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 will pay Hadasit 30% of all sublicensing payments made by said Strategic Partner to Cell Cure, 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 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 will pay Hadasit a 5% royalty on sales of products that utilize the licensed technology. Cell Cure will also pay sublicensing fees ranging from 10% to 30% of any payments Cell Cure 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 or a sublicensee other than a Strategic Partner paid royalties during the previous year, Cell Cure 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 does not grant a sublicense to a Strategic Partner and Cell Cure or a sublicensee (other than a Strategic Partner) conducts clinical trials of OpRegen®, Hadasit will be entitled to receive certain payments from Cell Cure upon the first attainment of certain clinical trial milestones in the process of seeking regulatory approval to market a product developed by Cell Cure 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 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 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 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, exclusive 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. 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. We will pay Cornell milestone payments upon the achievement of a research product sales milestone amount, and upon the attainment of certain FDA approval milestones. We will pay Cornell royalties on sales of licensed products and will share with Cornell a portion of any cash payments, other than royalties, received for the grant of sublicenses to non-affiliates. 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 has other industry standard termination rights.

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.

Asterias Cross-License Agreement

Under the terms of a Cross-License Agreement (the “Cross-License”) entered into by Asterias, BioTime, and ESI, BioTime and ESI received a fully-paid, non-royalty-bearing, world-wide, non-exclusive, sub-licensable license in, to, and under the certain Asterias patents and related patent rights for all purposes in the BioTime/ESI Licensed Field during the term of the license. The BioTime/ESI Licensed Field includes all fields of use except any and all applications (a) to treat disorders of the nervous system, (b) utilizing the immune system to prevent, treat, or cure cancer, and (c) involving the use of cells comprising, derived from, or manufactured using, human embryonic stem cells or human induced pluripotent stem cells for in vitro assay applications, including but not limited to drug discovery and development, drug monitoring, drug toxicology testing, and consumer products testing. BioTime has sublicensed its rights to certain subsidiaries.

Under the terms of the Cross-License, Asterias received a fully-paid, non-royalty-bearing, world-wide, non-exclusive, sub-licensable license under certain BioTime patents and related patent rights and ESI patents and related patent rights specified in the Cross-License, for all purposes in the Asterias Licensed Field during the term of the license. The Asterias Licensed Field includes all therapeutic applications of use for certain BioTime patents and ESI patents except all therapeutic applications of use involving pluripotent stem cell-derived cells of the following lineages: (a) bone and orthopedic soft tissues, including but not limited to ligament, tendon, meniscus, cartilage, and intervertebral disc; (b) vascular endothelium and perivascular cells including vascular smooth muscle and vascular pericytes; (c) adipose tissue; and (d) retinal pigment epithelium. The Asterias Licensed Field also includes all applications of use for certain

other BioTime patents involving live human pluripotent stem cell-derived cell therapies directed to the neural spinal cord (excluding cartilage and bone of the spine) and the myocardium; and also live human pluripotent stem cell-derived glial cell therapies directed to the central nervous system.

The term of the Cross-License shall expire on the expiration of the last claim within the Asterias patents rights or BioTime patent rights, as applicable, unless terminated earlier for a material breach by a party.

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Major Customers and Sources of Revenues

Major Sources of Revenues

The following table shows our major sources of revenues, as a percentage of total revenues, that were recognized during the years ended December 31, 2016, 2015, and 2014:

	Revenues for the Year ending December 31,					
Sources of Revenues	2016		2015		2014	
CIRM grant income	38.0	%	42.7	%	19.7	%
NIH grant income	-	%	6.5	%	12.5	%
IIA (formerly OCS) grant income (Cell Cure, Israel)	24.0	%	14.4	%	31.3	%
Subscriptions, advertising and other (various customers) [1]	35.0	%	29.4	%	32.5	%
Other [1]	3.0	%	7.0	%	4.0	%

(1) No individual customer greater than 5% of total revenues.

By Geographic Area

	Revenues for the Year Ended December 31,		
Geographic Area	2016	2015	2014
Domestic	$ 4,497	$ 5,976	$ 3,586
Asia	1,426	1,060	1,658
Total revenues	$ 5,923	$ 7,036	$ 5,244

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. In addition, from February 10, 2017 until May 31, 2017, we are subleasing a small portion of Asterias' facility. Our subsidiaries or affiliates, OncoCyte, OrthoCyte, and ReCyte Therapeutics are also conducting their research and development activities at our Alameda facility and OncoCyte is establishing a diagnostic laboratory there to conduct any cancer diagnostic tests that it may successfully develop.

Cell Cure leases approximately 1,128 square meters of office, laboratory, warehousing and cGMP production space located in Jerusalem, Israel.

Facilities Required—Laboratory Diagnostic Tests

OncoCyte constructed 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 must 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.

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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®.

Marketing

Online Database Products

LifeMap Sciences sells subscriptions to its database products to biotech and pharmaceutical companies worldwide. The GeneCards® Suite, includes GeneCards®, the leading human gene database, LifeMap Discovery® the database of embryonic development, stem cell research and regenerative medicine; and MalaCards™, the human disease database.

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 are directed to physicians and hospitals. 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. Warning and precaution information is required along with information about contraindications, adverse reactions, and certain recent studies. The warning and precautions include avoiding the use of Hextend® in patients with pre-existing renal dysfunction, that 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, that the use of Hextend® should be discontinued at the first sign of coagulopathy, and that the liver function of patients receiving hydroxyethyl starch products, including Hextend® should also be monitored.

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.

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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 are no assurances that any of our intellectual property rights 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, to protect and enforce our intellectual property rights, and to operate without infringing upon the proprietary rights of others if we are unable to obtain enabling licenses.

As of March 6, 2017, we owned or controlled or licensed directly or through our subsidiaries approximately 850 patents and pending patent applications worldwide including more than 180 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.”

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.

Cell Cure is presently a party to two pending opposition proceedings in the European Patent Office involving EP Patent Numbers 2147094 (issued 08-Oct-2014) and 2554661 (issued 19-Nov-2014), both entitled, "Stem Cell-Derived Retinal Pigment Epithelial Cells". The Oral Proceedings dates are 16-Mar-2017 and 17-Mar-2017, respectively. Both patents relate to our OpRegen® product and provide protection until April 2028. Cell Cure is vigorously defending these patents in the proceedings and does not believe the outcome will materially alter the protection or positioning of the OpRegen® product in the market. There are additional patent applications pending that if issued will provide further protection for OpRegen®.

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Patents Used in Our Stem Cell Business

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.

ViaCyte Patent Interference Proceedings

During May 2014, Asterias entered into a settlement agreement with ViaCyte, Inc. (“ViaCyte”) concerning certain litigations in several jurisdictions. 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 OncoCyte

OncoCyte’s diagnostic patent portfolio includes 13 patent families owned by OncoCyte 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, they have 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.

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OncoCyte 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, we have obtained from Wistar an exclusive option under which we may obtain licenses to 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. Those 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. Litigation, interferences, oppositions, inter partes reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. We may also face challenges to our patent and regulatory protections covering our products by third parties, including manufacturers of generics and biosimilars that may choose to launch or attempt to launch their products before the expiration of our patent or regulatory exclusivity. Litigation, interference, oppositions, inter partes reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our products, require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages against us that may exceed amounts, if any, accrued in our financial statements. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services.

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 engage. 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. 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 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.

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We believe that some of our competitors are trying to develop pluripotent cells 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 OpRegen®.

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. OncoCyte'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 OncoCyte'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 OncoCyte is developing.

Molecular diagnostic competitors in the category of OncoCyte'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, OncoCyte 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.

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.

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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.

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. In December 2016, in the 21st Century Cures Act adopted a new designation of Regenerative Advanced Therapy Designation. Under the 21st Century Cures Act, a drug is eligible for designation as a regenerative advanced therapy ("RAT") if: the drug is a regenerative medicine therapy, which is defined as a cell therapy, therapeutic

tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, except for those regulated solely under certain other sections. the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. Some of our current and future products may be eligible for RAT designation. RAT designation allows for similar benefits as the breakthrough therapy designation. There is no assurance that the FDA will grant breakthrough therapy, accelerated approval or RAT 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.

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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.

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.

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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.

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 the Clinical Laboratory Improvement Amendments of 1988, ("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 that 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.

OncoCyte 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.

FDA Regulation of Diagnostic Tests

OncoCyte's diagnostic tests will likely be classified as laboratory diagnostic tests ("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.

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On January 13, 2017, the FDA issued a Discussion Paper on LDTs ("Discussion Paper"), which follows the FDA's late 2016 announcement that contrary to its earlier reports, it would not issue a final guidance on its proposed oversight of LDTs and allow for further public discussion on appropriate oversight. As it did in its 2014 guidance documents, the FDA continues to advocate a risk based approach to LDT oversight and proposes focusing on new and significantly modified high and moderate risk LDTs; however, new and significantly modified LDTs in certain categories would not be expected to comply with premarket review, quality systems, and registration and listing requirements unless necessary to protect public health. These exempt categories include low risk LDTs, LDTs for rare diseases, traditional LDTs, LDTs intended solely for public health surveillance, certain LDTs used in CLIA certified labs, and LDTs intended solely for forensic use. Based on the FDA's guidance in the Discussion Paper, our products will likely not require FDA filing before launch. With respect to the postmarket surveillance of LDTs, the FDA's Discussion Paper recommends that laboratories initially report serious adverse events for all tests except the exempted categories if tests, which include LDTs intended for public health surveillance, some stem cell/tissue/organ transplantation LDTs, and LDTs intended solely for forensic use. The Discussion Paper notes that while the report neither represents the formal position of the FDA and nor is it a final version of the LDT guidance documents published in 2014, it is hoped that its publication will continue to advance further public disclosure.

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.

FDA regulations could also require, among other things, additional clinical studies and submission of a premarket notification or filing a Premarket Approval ("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.

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.

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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 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 devices, most Class II devices, 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.

Until all 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.

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.

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 that 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.

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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 2014 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.

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 OncoCyte 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 OncoCyte is engaged in the unauthorized corporate practice of medicine, OncoCyte could be required to restructure its contractual and other arrangements. In addition, violation of these laws may result in sanctions imposed against OncoCyte and/or the professional through licensure proceedings, and OncoCyte 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.

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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.

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.

Reimbursement

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

Sales of products are dependent on the availability and extent of coverage and reimbursement from third-party payers. In many markets around the world, these payers, including government health systems, private health insurers and other organizations, continue to be focused on reducing the cost of healthcare. Their efforts have intensified as a result of rising healthcare costs and economic challenges. Drugs, and in particular specialty drugs such as our products, remain a focus for cost containment by these parties. As a result, payers around the world are being more restrictive regarding the use of biopharmaceutical products while requiring a higher level of clinical evidence to support the benefit such products bring to patients and the broader healthcare system. The scrutiny of biopharmaceutical pricing in the United States remains intense and a point of focus in the discussion of rising healthcare costs. The pricing practices of certain companies have increased public media and government scrutiny of the biopharmaceutical industry, providing greater incentive for governments and private payers to limit or regulate the price of drug products and services. At the same time, value assessments of new technology, previously used predominantly outside the United States, are having an impact in the U.S. healthcare environment. Healthcare provider organizations and independent organizations are creating their own value assessments of biopharmaceutical drugs for comparison with manufacturer pricing. Although these organizations do not set drug prices, they seek to influence pricing as well as payer and provider decision making by publicly disclosing their assessments, often making assertions around what they believe to be the appropriate price to charge for a product. These developments put greater pressure on access to, pricing of and sales of products.

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In the United States, healthcare providers are reimbursed for covered services and products they deliver through Medicare, Medicaid and other government healthcare programs, as well as through private payers. Pharmacies are also reimbursed in a similar manner for drug products they dispense. We may be required to provide specified rebates or discounts on the products we sell to certain government funded programs, including Medicare and Medicaid, and those rebates or discounts have increased over time. The Patient Protection and Affordable Care Act (ACA), enacted in 2010, increased many of the mandatory discounts and rebates required of us and imposed a new Branded Prescription Pharmaceutical Manufacturers and Importers fee payable each year by us and other manufacturers. The new U.S. presidential administration has identified repealing and replacing the ACA as a priority. On March 6, 2017, the American Health Care Act ("AHCA") was introduced as the new administration's proposed replacement of ACA. The timing and method of repeal of the ACA and adoption of the AHCA remains uncertain, but impending changes will likely impact the number of patient lives covered, the quality of the insurance, Medicaid eligibility and the level of patient protections provided.

Further efforts by government agencies and state legislatures in the United States could also affect us and our industry. For example, a recently enacted Vermont law requires manufacturers to submit price increase justifications to the state attorney general if certain price increase and state spending thresholds are met. Examples of other proposals that have been discussed and debated, but not yet enacted, include state ballot initiatives that would place a maximum price ceiling, or cap, on pharmaceutical products purchased by state agencies and state legislative efforts to cap pharmaceutical prices for commercial payers. Other legislative and regulatory actions that would have a significant impact include: changes to how the Medicare program covers and reimburses current and future drugs, changes in the Federal payment rate or new rebate requirements for covered drugs and policies for payment in Medicare or Medicaid; and changes to coverage and payment for biosimilars, including the current Medicare biosimilar coverage and payment policies intended to encourage biosimilar adoption, or other policies that provide easier substitution or reimbursement advantages.

In the U.S. private sector, healthcare providers and payers continue to institute cost reduction and containment measures that lower drug spending altogether or shift a greater portion of the costs to patients. Such measures include more limited benefit plan designs, higher tier formulary placement that increases the level of patient out of pocket costs and stricter utilization criteria before a patient may get access to a drug. In the retail pharmacy sector, the use of such measures by Pharmacy Benefit Managers (PBMs) and insurers has continued to intensify which have limited product usage and revenues industry wide. PBMs are third-party organizations tasked with administrating prescription drug programs for large employers, health plans and government programs. Consolidation has resulted in a smaller number of PBMs and insurers overseeing a large portion of total covered lives in the United States; for example, three PBMs oversee approximately 75% of covered lives in the United States. As a result, PBMs and insurers have greater market power and negotiating leverage to exclude drugs from their formularies in favor of competitor drugs or alternative treatments, and/or to mandate stricter utilization criteria. Formulary exclusion effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. Utilization management requirements continue to be onerous for patients and physicians, limiting access to appropriate usage. In highly competitive treatment markets PBMs are also able to exert negotiating leverage by requiring incremental rebates from manufacturers in order to maintain their formulary position. A drug's favorable position on formulary is essential to ensure patients have access.

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

OncoCyte will face additional third-party reimbursement challenges for the diagnostic tests that it plans to provide. Revenues from OncoCyte'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 OncoCyte 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 OncoCyte; or

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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 OncoCyte may perform diagnostic tests will have Medicare as their primary medical insurance. We cannot assure that, without Medicare reimbursement OncoCyte's planned tests will produce sufficient revenues to enable OncoCyte to reach profitability and achieve its other commercial objectives.

Clinical diagnostic laboratory tests are generally reimbursed under the Medicare Clinical Laboratory Fee Schedule ("CLFS") and reimbursement under the Medicare program for the diagnostic tests that OncoCyte will offer is based on the CLFS.

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 CLFS. 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.

The Protecting Access to Medicare Act of 2014 ("PAMA"), enacted April 1, 2014 overhauls the CLFS payment methodology and imposes a market-based reimbursement system. PAMA provides that, in general payment for clinical diagnostic laboratory tests ("CLDTs") will be equal to the weighted median of private payer rates for the test, based on data reported by certain laboratories during a specified collection period. PAMA requires a similar rate adjustment and reporting requirement for advanced diagnostic laboratory tests ("ADLTs"). ADLTs are CDLTs furnished by a single laboratory, not sold for use by other entities, and meeting at least 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.

The tests OncoCyte will offer will most likely be classified as CDLTs.

On June 23, 2016, the CLFS final rule entitled "Medicare Program: Medicare Clinical Diagnostic Laboratory Test Payment System" ("Final Rule") set out the details of the payment policy mandated by PAMA and set an effective date of January 1, 2018 for the shift in payment rates. PAMA and the Final Rule will significantly impact the way that laboratory tests are reimbursed by Medicare. CMS estimates that the Final Rule will result in a reduction of approximately $390 million, or 5.6%, in Medicare spending on clinical laboratory tests in federal fiscal year 2018 and nearly $4 billion over the course of 10 years.

Beginning January 1, 2017, Medicare payment for any new ADLT will be based on the list price or charge. After the test is commercially available for three 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 CLDTs reimbursed under the CLFS, which would require OncoCyte to bill patients for these amounts. Because of the relatively low reimbursement for many CLDTs, 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.

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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. The predecessor to the current California MAC, 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, the MAC took the position that it would not cover any molecular diagnostic test unless the test is expressly included in a National Coverage Determination issued by CMS, or a Local Coverage Determination, or coverage article issued by the MAC. Denial of coverage for our diagnostic tests by the current California MAC, Noridian Healthcare Solutions, or reimbursement at inadequate levels, would have a material adverse impact on our 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 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.

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, 2016, we employed one hundred two employees (102), of which forty (40) are BioTime employees and sixty-two are employees of our subsidiaries (including OncoCyte and excluding Asterias), and one hundred (100) are on a full-time basis and two (2) persons on a part-time basis. Twenty-six (26) full-time employees hold Ph.D. degrees in one or more fields of science. None of our employees are covered by a collective bargaining agreement.

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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. Those of our subsidiaries and other affiliates within the BioTime Family of Companies that are developing therapeutic products derived from pluripotent stem cells will face substantially the same kind of risks that affect our business, as well as the risks related to our industry generally.

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 operating losses for the fiscal years ended December 31, 2016, 2015, and 2014 were $59 million, $65.8 million, and $50.7 million respectively, and we had an accumulated deficit of $196 million, as of December 31, 2016. We primarily finance our operations through the sale of equity securities, research grants, licensing fees, royalties on product sales by our licensees, 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. As a developer of therapeutic products derived from pluripotent stem cells, Asterias will face substantially the same kind of risks that affect our business, as well as the risks related to our industry generally.

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

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

The experimentation we are doing is costly, time consuming, and uncertain as to its results. We incurred research and development expenses amounting to $36.1 million, $42.6 million, and $37.5 million during the years ended December 31, 2016, 2015, and 2014, respectively.

If we are successful in developing a new technology or product, refinement of the new technology or product and definition of the practical applications and limitations of the technology or product may take years and require the expenditure of large sums of money. 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 other companies or we may discontinue one or more of the research or product development programs. Any such arrangements may be dilutive to our ownership or economic interest in the products.

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 to manufacture OpRegen®.

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.

There also is a risk that our competitors may succeed at developing safer or more effective products that could render our products and technologies obsolete or noncompetitive.

We will need to issue additional equity or debt securities in order to raise additional capital needed to pay our operating expenses

We and the other members of the BioTime Family of Companies, including Asterias and OncoCyte, plan to continue to incur substantial research and product development expenses and will need to raise additional capital to pay operating expenses.

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The ability of BioTime, Asterias and OncoCyte to raise additional equity or debt capital will depend, not only on progress made in developing new products and technologies, but also on access to capital and conditions in the capital markets. There is no assurance that we or Asterias and OncoCyte 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.

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 processes and 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. We may not be able to sell our products in sufficient volumes to recover our costs or to earn a profit.

We 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 face the risk of incurring liabilities to clinical trial patients if they incur any injuries as a result of their participation in the clinical trials. We will also be obligated to obtain information and prepare reports about the health of the clinical trial patients. We are not aware of any claims by patients alleging injuries suffered as a result of any of our 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, 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.

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, 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, 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. 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.

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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 and regulatory changes that could delay, limit, or prevent regulatory agency approvals.

- 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 it deems necessary.

We will face similar regulatory issues in foreign countries.

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;

negative or inconclusive results from clinical trials;

unforeseen side effects, possibly resulting in the FDA or other regulatory authorities denying approval of our product candidates;

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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 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.

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 may give rise to religious, moral, and ethical issues. 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 in all key markets.

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 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.

Litigation, interferences, oppositions, inter partes reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. This means that patents owned or licensed by us may be lost if the outcome of a proceeding is unfavorable to us.

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

Our success depends in part on our ability to obtain and defend patent and other intellectual property rights that are important to the commercialization of our products and product candidates. The degree of patent protection that will be afforded to our products and processes in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, administrative bodies and lawmakers in these countries. We can provide no assurance that we will successfully obtain or preserve patent protection for the technologies incorporated into our products and processes, or that the protection obtained will be of sufficient breadth and degree to protect our commercial interests in all countries where we conduct business. If we cannot prevent others from exploiting our inventions, we will not derive the benefit from them that we currently expect. Furthermore, we can provide no assurance that our products will not infringe patents or other intellectual property rights held by third parties.

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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.

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. Until we 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 ACA and future changes to that law may adversely affect our business

As a result of the adoption of the ACA, in the United States, substantial changes have been made to the system for paying for healthcare in the United States. 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. Certain provisions related to cost-savings and reimbursement measures could adversely affect our future financial performance.

If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business

Our activities, and the activities of the BioTime Family of Companies, our collaborators, distributors and other third-party providers, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and

promotion, product distribution, adverse event reporting and product risk management. Our interactions in the U.S. or abroad with physicians and other health care providers that prescribe or purchase our products are also subject to government regulation designed to prevent fraud and abuse in the sale and use of the products and place greater restrictions on the marketing practices of health care companies. Health care companies such as ours are facing heightened scrutiny of their relationships with health care providers from anti-corruption enforcement officials. In addition, health care companies such as ours have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of health care business, submission of false claims for government reimbursement, antitrust violations or violations related to environmental matters. Risks relating to compliance with laws and regulations may be heightened as we continue to operate globally.

Regulations governing the health care industry are subject to change, with possibly retroactive effect, including:

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- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, pricing or marketing practices, compliance with wage and hour laws and other employment practices, method of delivery, payment for health care products and services, compliance with health information and data privacy and security laws and regulations, tracking and reporting payments and other transfers of value made to physicians and teaching hospitals, extensive anti-bribery and anti-corruption prohibitions, product serialization and labeling requirements and used product take-back requirements;

- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;

- requirements that provide for increased transparency of clinical trial results and quality data, such as the EMA's clinical transparency policy, which could impact our ability to protect trade secrets and competitively-sensitive information contained in approval applications or could be misinterpreted leading to reputational damage, misperception or legal action which could harm our business; and

- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products.

Violations of governmental regulation may be punishable by criminal and civil sanctions against us, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid, as well as against executives overseeing our business. In addition to penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors, or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government. We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, collaborators, partners or third-party providers that would violate the laws or regulations of the jurisdictions in which we operate. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business.

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.

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 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 may choose to partner on one or more products for marketing, selling or distributing our products. If we do not partner for commercial services, 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 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 trials 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 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 and a discussion paper 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 the new regulatory measures set forth in these documents:

·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.

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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. It generally takes two to three years to obtain Medicare coverage and other third party reimbursement approvals for a new LDT and there can be no assurance OncoCyte will obtain such approvals for any of the cancer diagnostics that it is developing. Until a new cancer diagnostic test is accepted by third party payers for reimbursement, OncoCyte will have to market the test to physicians on a patient pay basis. In the absence of reimbursement by Medicare, patients who would be candidates for the use of OncoCyte's diagnostic tests and who rely on Medicare coverage may decline to use those tests, and physicians may be reluctant to prescribe the tests, due to the cost of the test to the patients. Because of this patient cost factor, revenues from any new cancer test that OncoCyte markets will experience slow growth until the test is approved for reimbursement in an amount commensurate with the cost to the patient.

Medicare and other third-party payers may change their coverage policies or cancel future contracts with OncoCyte at any time; review and adjust the rate of reimbursement; or stop paying for OncoCyte's tests altogether, which would reduce OncoCyte's total revenues. 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 diagnostic tests may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to OncoCyte. Any such action could have a negative impact on OncoCyte's revenues, which may have a material adverse effect on its financial condition, results of operations and cash flows.

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

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 OncoCyte's diagnostic tests. The new U.S. presidential administration has identified repealing and replacing the ACA as a priority. On March 6, 2017, the American Health Care Act ("AHCA") was introduced as the new administration's proposed replacement of ACA. The timing and method of repeal of ACA and adoption of the AHCA remains uncertain, but impending changes will likely impact the number of patient lives covered, the quality of the insurance, Medicaid eligibility and the level of patient protections provide.

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 OncoCyte to bill patients for these amounts. In the event that Congress were to ever enact such legislation, the cost of billing and collecting for OncoCyte's tests could often exceed the amount actually received from the patient.

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

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

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

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.

Our net income or loss will be impacted by changes in the market value of Asterias and OncoCyte common stock

Because we use the equity method of accounting for the common stock of Asterias and OncoCyte that we hold at fair value, we will recognize gain or loss to the extent that the market value of Asterias and OncoCyte common stock changes from calendar quarter to calendar quarter, regardless of whether we sell any of those 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 152,000,000 shares of capital stock consisting of 150,000,000 common shares and 2,000,000 “blank check” preferred shares. As of December 31, 2016, there were 103,396,245 common shares outstanding of which 619,706 were held by our subsidiaries, 6,958,458 common shares reserved for issuance upon the exercise of outstanding options under our employee stock option plans; 100,000 common shares reserved for issuance upon the lapse of RSUs under our employee stock option plan; and 9,394,862 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.

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

The operation of some 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.

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The implementation of a new FASB accounting standard could increase the risk that our future consolidated financial statements could be qualified by going concern uncertainty

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” ASU No. 2014-15 defines management’s responsibility to assess an entity’s ability to continue as a going concern, and to provide related footnote disclosures. ASU No. 2014-15 is effective for us for the year ended December 31, 2016, and all annual and interim periods thereafter. In connection with preparing consolidated financial statements for each annual and interim reporting period, ASU No. 2014-15 requires that an entity’s management evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the consolidated financial statements are issued (or within one year after the date that the consolidated financial statements are available to be issued when applicable). As a result of the implementation of ASU No. 2014-15, we will be required to have more cash, cash equivalents, and liquid investments on hand on the date we issue or file our consolidated financial statements than had been the case during prior years in order to avoid a going concern qualification in our auditor’s report and in the footnotes to our consolidated financial statements. If our consolidated financial statements were to become subject to a going concern qualification or uncertainty or if we are unable to alleviate substantial doubt as part of our going concern assessment, or both, the market price of our common stock could decline.

Asterias and OncoCyte will also be impacted by ASU No. 2014-15 in much the same manner as us. If the financial statements of Asterias, or OncoCyte, or both, were to become subject to a going concern qualification or uncertainty, the market price of their common stock could decline, resulting in a loss or decline in value of the Asterias shares we own, the OncoCyte shares we own, or both, as equity method investments at fair value.

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:

Lease Year	Annual Base Rent	Monthly Installment 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 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.

From February 10, 2017 until May 31, 2017, we are subleasing a small portion of Asterias' facility in Fremont, California for $38,000 per month.

Cell Cure Facilities

Cell Cure has leased approximately 1,128 square meters of office and laboratory space in Jerusalem, Israel under a lease that expires between May 30, 2019 and December 31, 2020, with two additional options to extend the lease for 5 years each. Base monthly rent is approximately NIS 55,218 (approximately US $14,400 per month). In addition to base rent, Cell Cure 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.

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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. Cell Cure is presently a party to two pending opposition proceedings in the European Patent Office involving EP Patent Numbers 2147094 (issued 08-Oct-2014) and 2554661 (issued 19-Nov-2014), both entitled, “Stem Cell-Derived Retinal Pigment Epithelial Cells”. The Oral Proceedings dates are March 16, 2017 and March 17, 2017, respectively. Both patents relate to our OpRegen® product and provide protection until April 2028. Cell Cure is vigorously defending these patents in the proceedings and does not believe the outcome will materially alter the protection or positioning of the OpRegen® product in the market. There are additional patent applications pending that if issued will provide further protection for OpRegen®.

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, 2015 and 2016, as reported by the NYSE MKT:

Quarter Ended	High	Low
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
March 31, 2016	$3.68	$2.08
June 30, 2016	$3.25	$2.29
September 30, 2016	$3.97	$2.70
December 31, 2016	$3.89	$2.89

As of February 28, 2017, there were 15,377 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, 2016 (in thousands, except weighted average exercise prices):

Plan Category	Number of Shares to be Issued upon Exercise of Outstanding Options and Vesting of Restricted Stock Units, and Rights		Weighted Average Exercise Price of the Outstanding Options, and Rights	Number of Shares Remaining Available for Future Issuance under Equity Compensation Plans
BioTime Equity Compensation Plans Approved by Shareholders[1]	7,058	(1)	$ 3.60	2,894

(1) Includes 100,000 outstanding Restricted Stock Units, or RSUs.

The following table shows certain information concerning the options outstanding and available for issuance under all of the compensation plans and agreements for our consolidated subsidiary companies as of December 31, 2016 (in thousands, except weighted average exercise price per share):

Number of Shares to be Issued upon Exercise of	Weighted Average Exercise Price of the Outstanding Options,	Number of Shares Remaining Available for Future Issuance

	Outstanding Options and Rights	and Rights	under Equity Compensation Plans
OrthoCyte Equity Compensation Plans Approved by Shareholders[1]	1,300	$ 0.06	2,700
OncoCyte Equity Compensation Plans Approved by Shareholders[1]	3,017	$ 2.52	880
ReCyte Therapeutics Equity Compensation Plans Approved by Shareholders[1]	1,250	$ 2.05	2,750
BioTime Asia Equity Compensation Plans Approved by Shareholders[1]	300	$ 0.01	1,300
Cell Cure Compensation Plans Approved by Shareholders[1][2]	81	$ 38.00	44
LifeMap Sciences Equity Compensation Plans Approved by Shareholders[1]	1,596	$ 1.44	746
LifeMap Solutions Compensation Plans Approved by Shareholders[1]	12	$ 500.00	7

(1) BioTime is, directly or through one or more subsidiaries, the majority shareholder. Except for OncoCyte, all other common stock underlying the stock options under the respective equity plans are privately-held.

(2) Cell Cure Share Option Plan US dollar exercise price is approximated based on the conversion rate between the US dollar and the New Israeli Shekel, NIS, at the time of grant. The exercise price is denominated in NIS and is 154 per share.

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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.

We have in the past distributed common stock of a subsidiary to our shareholders, on a pro rata basis, as a dividend in kind. We may distribute shares of subsidiaries or affiliated companies again in the future and any such distribution 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.

Performance Measurement Comparison[(1)]

The following graph compares total stockholder returns of BioTime, Inc. for the last five fiscal years beginning December 31, 2011 to two indices: the NYSE Amex Market Value – U.S. Companies (Amex Market Value) and the NYSE Arca Biotechnology Index (NYSE Arca Biotechnology Index). The total return for our stock and for each index assumes the reinvestment of dividends, although we have never declared dividends on BioTime stock, and is based on the returns of the component companies weighted according to their capitalizations as of the end of each quarterly period. The NYSE 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

		2011	2012	2013	2014	2015	2016
BioTime, Inc.	Return %		-45.96	14.65	3.61	9.92	-4.53
	Cum $	100.00	54.04	61.96	64.20	70.57	67.37
AMEX Market Value (US Companies)	Return %		9.84	10.23	5.09	-22.23	12.45
	Cum $	100.00	109.84	121.09	127.25	98.96	111.28
NYSE Arca Biotechnology Index	Return %		41.88	50.80	47.91	11.39	-19.15
	Cum $	100.00	141.88	213.96	316.48	352.53	285.03

(1) 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 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, 2011. The cumulative total return on BioTime common shares has been computed based on a price of $5.81per share, the price at which BioTime’s common

shares closed on December 31, 2011.

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

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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,				
REVENUES:	2016	2015	2014	2013	2012
Grant income	$3,671	$4,502	$3,297	$1,573	$2,222
Royalties from product sales and license fees	544	719	398	367	542
Subscription and advertisement	972	1,357	1,173	2,218	900
Sales of research products and services	736	458	376	276	251
Total revenues	5,923	7,036	5,244	4,434	3,915
Cost of sales	(358)	(1,107)	(837)	(793)	(434)
Gross profit	5,565	5,929	4,407	3,641	3,481
OPERATING EXPENSES:					
Research and development	(36,106)	(42,604)	(37,533)	(26,609)	(18,117)
Acquired in-process research and development [1]	-	-	-	(17,459)	-
General and administrative	(28,426)	(29,134)	(17,556)	(15,559)	(10,365)
Total operating expenses	(64,532)	(71,738)	(55,089)	(59,627)	(28,482)
Loss from operations	(58,967)	(65,809)	(50,682)	(55,986)	(25,001)
OTHER INCOME/(EXPENSE):					
Interest income/(expense), net	(747)	(340)	(89)	-	19
BioTime's share of losses and impairment in equity method investment in Ascendance	(4,671)	(35)	-	-	-
Gain on deconsolidation of Asterias	49,048	-			
Gain on equity method investment in Asterias at fair value	34,361	-	-	-	-
Gain on investment	-	3,694	-	-	-
Other (expense)/income, net	(403)	(160)	(384)	(204)	(324)
Total other (expenses)/income, net	77,588	3,159	(473)	(204)	(305)
INCOME (LOSS) BEFORE INCOME TAX BENEFITS	18,621	(62,650)	(51,155)	(56,190)	(25,306)
Deferred income tax benefit	-	4,516	7,376	3,281	-
NET INCOME (LOSS)	18,621	(58,134)	(43,779)	(52,909)	(25,306)
Net loss attributable to noncontrolling interest	14,951	11,143	7,367	9,026	3,880
NET INCOME (LOSS) ATTRIBUTABLE TO BIOTIME, INC.	33,572	(46,991)	(36,412)	(43,883)	(21,426)
Dividends on preferred shares	-	(415)	(87)	-	-
NET INCOME (LOSS) ATTRIBUTABLE TO BIOTIME, INC. COMMON SHAREHOLDERS	$33,572	$(47,406)	$(36,499)	$(43,883)	$(21,426)
NET INCOME (LOSS) PER COMMON SHARE					
BASIC	$0.35	$(0.59)	$(0.55)	$(0.81)	$(0.44)
DILUTED	$0.34	$(0.59)	$(0.55)	$(0.81)	$(0.44)

WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK OUTSTANDING:					
BASIC	97,316	79,711	66,467	54,226	49,214
DILUTED	99,553	79,711	66,467	54,226	49,214

(1) Represents the value of incomplete research and development projects acquired by Asterias from Geron Corporation under an Asset Contribution Agreement.

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	December 31, 2016[2]	2015	2014	2013	2012
Consolidated Balance Sheet Data (in thousands):					
Cash and cash equivalents	$22,088	$42,229	$29,487	$5,495	$4,350
Total assets	142,572	94,660	74,901	57,730	29,749
Total liabilities	12,064	18,213	12,178	15,467	5,454
Accumulated deficit	(196,321)	(229,893)	(182,190)	(145,778)	(101,896)
Total shareholder's equity	$130,508	$76,447	$62,723	$42,262	$24,294

(2) Reflects the effect of the Asterias Deconsolidation that occurred on May 13, 2016. See Note 3 to our consolidated financial statements included elsewhere in this Report.

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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 three-year period ended December 31, 2016, 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, 2016 as compared to the year ended December 31, 2015, and during the year ended December 31, 2015 as compared to the year ended December 31, 2014. This discussion should be read in conjunction with our consolidated financial statements for the three-year period ended December 31, 2016 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 Report, particularly in "Item 1A. Risk Factors."

Critical Accounting Policies

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts in our consolidated financial statements and related notes. Our significant accounting policies are described in Note 2 to our consolidated financial statements included elsewhere in this Report. We have identified below our critical accounting policies and estimates that we believe require the greatest amount of judgment. On an ongoing basis, we evaluate estimates which are subject to significant judgment, including those related to going concern assessment of our consolidated financial statements, useful lives associated with long-lived assets, including evaluation of asset impairment, allowances for uncollectible accounts receivables, valuing shares owned in nonconsolidated companies using the equity method of accounting, loss contingencies, deferred income taxes and tax reserves, including valuation allowances related to deferred income taxes, and assumptions used to value stock-based awards, debt or other equity instruments. Actual results could differ materially from those estimates. On an ongoing basis, we evaluate our estimates compared to historical experience and trends which form the basis for making judgments about the carrying value of assets and liabilities. To the extent that there are material differences between our estimates and our actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

We believe the assumptions and estimates associated with the following have the greatest potential impact on our consolidated financial statements.

Going concern assessment – With the implementation of FASB's new standard on going concern, ASU No. 2014-15, beginning with the year ended December 31, 2016 and all annual and interim periods thereafter, we will assess going concern uncertainty in our consolidated financial statements to determine if we have sufficient cash and cash equivalents on hand and working capital to operate for a period of at least one year from the date our consolidated financial statements are issued or are available to be issued, which is referred to as the "look-forward period" as defined by ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we will consider various scenarios, forecasts, projections, and estimates, and we will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and our ability to delay or curtail those expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions concerning our ability to curtail or delay research and development programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

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 is recognized as revenue when the related research and development expenses are incurred. Revenues from the sale of research products and services are primarily derived from the sale of hydrogels and stem cell products and are recognized when earned. Royalty revenues consist of product royalty payments. We recognize revenue in the quarter in which the royalty reports are received rather than the quarter in which the sales took place. 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 applicable subscription or advertising periods. 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, subject to substantial uncertainty, 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.

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Equity method accounting for Asterias, at fair value – We use the equity method of accounting when we have the ability to exercise significant influence, but not control, as determined in accordance with GAAP, over the operating and financial policies of a company in which we hold an equity interest. For equity method investments, which we have elected to measure at fair value, unrealized gains and losses are reported in the consolidated statements of operations as a non-operating gain or loss from equity method investments. See Note 4 to our consolidated financial statements included elsewhere in this Report.

Investments in Common Stock of Privately Held Companies – We evaluate whether our ownership of common stock of a company requires consolidation of the company under, first, the variable interest entity ("VIE") model, and then under the Voting Interest model, in accordance with accounting guidance for consolidations under Accounting Standards Codification ("ASC") 810-10. If consolidation of the company is not required under either the VIE model or the Voting Interest model, we determine whether the equity method of accounting should be applied in accordance with ASC 323, Investments – Equity Method and Joint Ventures. The equity method of accounting applies to investments in common stock or in-substance common stock of a company if we exercise significant influence over, but does not control, the company, which typically occurs if we own 20% or more, but less than a majority, of the voting interests of a company.

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

We review 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, we write down the investment to fair value. Based on our evaluation and continuing losses and negative cash flows generated from our interest in Ascendance, including uncertainty as to Ascendance's ability to raise sufficient financing, we determined that an other-than-temporary impairment existed with respect to the Ascendance common stock we owned as of December 31, 2016, and we wrote down the entire carrying value of that investment as of that date. See Note 2 to our consolidated financial statements included elsewhere in this Report.

Long-lived intangible assets – Long-lived intangible assets, consisting primarily of acquired patents, patent applications, and licenses to use certain patents are stated at acquired cost, less accumulated amortization. Amortization expense is computed using the straight-line method over the estimated useful lives of the assets, generally over 10 years.

Impairment of long-lived assets – Our long-lived assets, including long-lived 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.

Research and development – Research and development expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct and research-related overhead expenses including salaries, payroll taxes, consulting fees, research and laboratory fees, rent of research facilities, amortization of intangible assets, costs of patent applications, prosecution and maintenance, and license fees paid to third parties to acquire patents or licenses to use patents and other technology. We expense research and development costs as incurred. Research and development expenses incurred and reimbursed by grants from third parties approximate the grant income recognized in the consolidated statements of operations.

Stock-based compensation – We follow accounting standards governing share-based payments, which require the measurement and recognition of compensation expense for all share-based compensation awards made to directors and employees, including employee stock options, based on estimated fair values, less estimated forfeitures. 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 complex and subjective variables. These variables include, but are not limited to, expected stock price volatility over the term of the awards, and the expected term of options granted, derived from 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.

As disclosed in Note 10 to our consolidated financial statements, certain of our privately-held consolidated subsidiaries have their own share-based compensation plans. For share-based compensation awards granted by our privately-held consolidated subsidiaries under their respective equity plans, we determine the expected stock price volatility using historical prices of comparable public company’s common stock for a period equal to the expected term of the options. The expected term of those privately-held company options is based upon the “simplified method” provided under Staff Accounting Bulletin, Topic 14, or SAB Topic 14. The fair value of the shares of common stock underlying the stock options of these privately-held consolidated subsidiaries is determined by the Board of Directors of those subsidiaries, as applicable, which is also used to determine the exercise prices of those stock options at the time of grant.

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Although the fair value of employee stock options is determined in accordance with FASB guidance, changes in the assumptions can materially affect the estimated value and therefore the amount of compensation expense recognized in the consolidated financial statements.

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 registered the BioTime common shares held by our subsidiaries for sale under the Securities Act of 1933, as amended (the "Securities Act") to enhance the marketability of the shares. See Note 9 to the consolidated financial statements.

Accounting for warrants – We determine the accounting classification of warrants that we or our subsidiaries issue, as either liability or equity classified, by assessing whether the warrants meet liability classification, first, in accordance with ASC 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, and then in accordance with ASC 815-40, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock. Under ASC 480, warrants are classified as a liability if the warrants are mandatorily redeemable, obligate us to settle the warrants or the underlying shares by paying cash or other assets, or the warrants must or may require settlement by issuing a variable number of shares. If warrants do not meet liability classification under ASC 480-10, we assess the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, in order to conclude equity classification, we also assess whether the warrants are indexed to our or our subsidiary's common stock, as applicable, and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments are made, we conclude whether the warrants are classified as liability or equity. Liability classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded in the consolidated statements of operations as a gain or loss. Equity classified warrants are accounted for at fair value on the date of issuance with no changes in value recognized subsequent to the issuance date. We do not have any liability classified warrants as of any period presented. See Note 9 to the consolidated financial statements.

Income taxes – We account for income taxes in accordance with ASC 740, Income Taxes, which prescribe the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. ASC 740 guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. We file a U.S. federal income tax return as well as various state and foreign income tax returns. Our judgments regarding future taxable income may change over time due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. Certain majority-owned subsidiaries that we consolidate under GAAP file their own, standalone federal income tax returns as those subsidiaries are not considered consolidated under federal income tax regulations, and accordingly, we may not use the tax attributes of those subsidiaries for our income taxes. If our assumptions, and consequently our estimates, change in the future with respect to our own deferred tax assets and liabilities, the valuation allowance may be increased or decreased, which may have a material impact on our consolidated statements of operations.

As further discussed in Note 12 to our consolidated financial statements, we adopted early the provisions of Accounting Standards Update, ASU 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes, on a retrospective basis and due to the full valuation allowance on our deferred tax assets for all periods presented. The adoption did not have any impact on the consolidated financial statements.

Principles of consolidation – Our consolidated financial statements include the accounts of our subsidiaries ESI, 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.

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As further discussed in Notes 3 and 4 to our consolidated financial statements, effective May 13, 2016, we deconsolidated Asterias financial statements and results of operations due to the decrease in our percentage ownership in Asterias from 57.1% to 48.7% as a result of Asterias' public offering of its common stock to raise capital for its operations (the "Asterias Deconsolidation"). On May 13, 2016, we experienced a loss of control of Asterias under GAAP. Loss of control is deemed to have occurred when, among other things, a parent company owns less than a majority of the outstanding common stock in the subsidiary, lacks a controlling financial interest in the subsidiary and, is unable to unilaterally control the subsidiary through other means such as having, or being able to obtain, the power to elect a majority of the subsidiary's Board of Directors based solely on contractual rights or ownership of shares holding a majority of the voting power of the subsidiary's voting securities. All of these loss-of-control factors were present for with respect to our interest in Asterias as of May 13, 2016. Accordingly, since May 13, 2016, we have accounted for Asterias using the equity method of accounting at fair value. Our consolidated financial statements present the operating results of all of our wholly-owned and majority-owned subsidiaries that we consolidate as required under GAAP. Although beginning on May 13, 2016, Asterias' financial statements and results will no longer be part of our consolidated financial statements and results, the market value of the Asterias common stock we hold will be reflected on our consolidated balance sheet and changes in the market value of those shares will be reflected in our consolidated statements of operations, allowing our shareholders to evaluate the value of the Asterias portion of our business.

As further discussed in Note 16 to the consolidated financial statements, on February 17, 2017, we deconsolidated OncoCyte's financial statements from our consolidated financial statements due to our "loss of control" of OncoCyte under GAAP as a result of the decrease in our percentage ownership in OncoCyte from 51.1% to 49.9% following the exercise of OncoCyte stock purchase warrants by certain investors (the "OncoCyte Deconsolidation). Beginning on February 17, 2017, we will account for the OncoCyte common stock we hold using the equity method of accounting at fair value. Although beginning on February 17, 2017, OncoCyte's financial statements and results will no longer be part of our consolidated financial statements and results, the market value of the OncoCyte common stock we hold will be reflected on our consolidated balance sheet and changes in the market value of those shares will be reflected in our consolidated statements of operations, allowing our shareholders to evaluate the value of the OncoCyte portion of our business. The financial statement effect of the OncoCyte Deconsolidation will be reported for the quarter ending March 31, 2017, and is expected to result in an unrealized gain on deconsolidation in our consolidated statements of operations.

Results of Operations

Comparison of Years Ended December 31, 2016 and 2015

To provide proper comparability of the results of BioTime due to the Asterias Deconsolidation, the following tables provide consolidated results of operations of BioTime for the years ended December 31, 2016 and 2015, then show the results operations of Asterias that are included in BioTime's consolidated results, which include the periods from January 1, 2016 through May 12, 2016 (133 days) and, for the year ended December 31, 2015, after intercompany eliminations, to arrive at the BioTime consolidated results less Asterias (in thousands).

	Year Ended December 31, 2016			Year Ended December 31, 2015		
	Consolidated Results of Operations	Asterias (133 days)	Consolidated Results less Asterias	Consolidated Results of Operations	Asterias	Consolidated Results less Asterias
REVENUES:						
Grant income	$ 3,671	$ 2,247	$ 1,424	$ 4,502	$ 3,007	$ 1,495
Royalties from product sales and license fees	544	107	437	719	535	184

Subscription and advertising	972	-	972	1,357	-	1,357
Sale of research products and services	736	-	736	458	40	418
Total revenues	5,923	2,354	3,569	7,036	3,582	3,454
Cost of sales	(358)	(53)	(305)	(1,107)	(268)	(839)
Gross profit	$ 5,565	$ 2,301	$ 3,264	$ 5,929	$ 3,314	$ 2,615

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Revenues

The following tables show our consolidated revenues for the years ended December 31, 2016 and 2015 (amounts in thousands).

	Year Ended December 31,		$ Increase/ Decrease	% Increase/ Decrease
	2016	2015		
Grant income	$ 3,671	$ 4,502	$ -831	-18%
Royalty from product sales and license fees	544	719	-175	-24%
Subscription and advertising	972	1,357	-385	-28%
Sales of research products and services	736	458	+278	+61%
Total revenues	5,923	7,036	-1,113	-16%
Cost of sales	(358)	(1,107)	-749	-68%
Gross profit	$ 5,565	$ 5,929	$ -364	-6%

For the year ended December 31, 2016, total consolidated revenues decreased by $1.1 million as compared to the same period in 2015 primarily due to the Asterias Deconsolidation which resulted in the exclusion of Asterias revenue from our financial results after May 12, 2016. Revenues, net of Asterias, were relatively unchanged in 2016 compared to 2015 at $3.6 million and $3.5 million, respectively BioTime grant income, net of Asterias, for 2016, was entirely from grants awarded to Cell Cure by the Israel Innovation Authority, or IIA (formerly the Office of the Chief Scientist of Israel) of the Ministry of Economy and Industry, for the development of OpRegen® while in 2015, grant income, net of Asterias, was from the IIA of $1.0 million to Cell Cure and $0.5 million from the National Institutes of Health.

Our subscription and advertising revenues amounted to $1.0 million and $1.4 million for the years ended December 31, 2016 and 2015, respectively. Subscription and advertising revenues entirely represent subscription and advertising revenues from LifeMap Science's online database business primarily related to its GeneCards® database.

Revenues from the sale of research products and services in 2015 were primarily derived from the sale of hydrogels and stem cell products by our former ESI-BIO division. During December 2015, we contributed or licensed rights to sell those research products to Ascendance in exchange for shares of Ascendance common stock, and as a result, revenues from sales of those products decreased by $0.4 million in 2016. Service revenues of $0.7 million in 2016 were primarily generated by LifeMap Solutions from mobile health software development performed for its customers.

Cost of sales for the year ended December 31, 2016 as compared to 2015 decreased in line with the decrease in the various streams of revenues other than grant income, also contributed by the deconsolidation of Asterias related cost of sales.

Operating Expenses

The following table shows our consolidated operating expenses for the years ended December 31, 2016 and 2015 (in thousands).

	Years Ended December 31,		$ Increase/	% Increase/
	2016	2015	Decrease	Decrease
Research and development expenses	$ 36,106	$ 42,604	$ -6,498	- 15%
General and administrative expenses	28,426	29,134	-708	-2%

Year Ended December 31, 2016	Year Ended December 31, 2015

	Consolidated Results of Operations	Asterias (133 days)	Consolidated Results less Asterias	Consolidated Results of Operations	Asterias	Consolidated Results less Asterias
OPERATING EXPENSES:						
Research and development	$ 36,106	$ 8,684	$ 27,422	$ 42,604	$ 17,322	$ 25,282
General and administrative	28,426	7,561	20,865	29,134	7,711	21,423

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Research and development expenses

Total research and development expenses decreased by $6.5 million to $36.1 million in 2016 from $42.6 million in 2015. The decrease is attributable primarily to the Asterias Deconsolidation which resulted in the exclusion of Asterias expenses after May 12, 2016. Research and development expenses attributable to BioTime, net of Asterias, increased approximately $2.1 million or 8% to $27.4 million for the year ended December 31, 2016, from $25.3 million during 2015. The increase is primarily attributable to the development of PureStem® progenitor and pluripotent cell lines and related research products by BioTime, the development of OpRegen® by Cell Cure, and the development of cancer diagnostic tests by OncoCyte. These expenses include consulting and outside research and services, including stock-based compensation to consultants, and regulatory and clinical trials of BioTime's Renevia®, Cell Cure OpRegen®, and OncoCyte's cancer diagnostic tests.

The following table shows the approximate amounts and percentages of our total research and development expenses of $36.1 million and $42.6 million allocated to our primary research and development programs during the years ended December 31, 2016 and 2015, respectively (amounts in thousands).

		Amount[1]		Percent	
Company	Program	2016	2015	2016	2015
BioTime and ESI	PureStem® progenitor and pluripotent cell lines, and related research products	$6,060	$5,196	16.8 %	12.2 %
BioTime	Renevia® and other HyStem® products and research	3,856	4,047	10.7 %	9.5 %
BioTime	Hextend®	54	59	0.1 %	0.1 %
Cell Cure[2]	OpRegen®	4,803	4,086	13.3 %	9.6 %
OrthoCyte	Orthopedic therapy	606	590	1.7 %	1.4 %
ReCyte Therapeutics	Cardiovascular therapy	949	1,142	2.6 %	2.7 %
Subtotal therapeutic projects		16,328	15,120	45.2 %	35.5 %
Asterias[3]	Pluripotent cell therapy programs	8,684	17,322	24.1 %	40.7 %
LifeMap Sciences[4]	Databases and mobile health products	5,348	5,251	14.8 %	12.3 %
OncoCyte	Cancer diagnostics	5,746	4,911	15.9 %	11.5 %
Subtotal non-therapeutic projects		11,094	10,162	30.7 %	23.8 %
Total projects		$36,106	$42,604	100.0%	100.0%

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

(2) Cell Cure expenses, although shown at 100% in the table, are funded 75% by BioTime and 25% by non-controlling interests in Cell Cure.

(3) Amounts for 2016 include only the period from January 1 through May 12, 2016, due to the deconsolidation of Asterias.

(4) Includes LifeMap Solutions, Inc., a wholly-owned subsidiary of LifeMap Sciences.

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General and administrative expenses

The following table shows the amount and approximate percentages of our total general and administrative expenses of $28.4 million and $29.1 million allocated to BioTime and our subsidiaries during the years ended December 31, 2016 and 2015, respectively (amounts in thousands).

	Amount[1]		Percent	
Company	2016	2015	2016	2015
BioTime	$8,958	$9,761	31.5%	33.5%
Cell Cure[4]	1,185	655	4.2%	2.2%
OrthoCyte	570	582	2.0%	2.0%
ReCyte Therapeutics	581	760	2.0%	2.6%
ESI	276	245	1.0%	0.9%
Subtotal therapeutic entities	11,570	12,003	40.7%	41.2%
Asterias[2]	7,561	7,711	26.6%	26.5%
LifeMap Sciences[3]	3,385	5,142	11.9%	17.6%
OncoCyte	5,910	4,278	20.8%	14.7%
Subtotal non-therapeutic entities	9,295	9,420	32.7%	32.3%
Total	$28,426	$29,134	100.0%	100.0%

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

(2) Amounts for 2016 include only the period from January 1 through May 12, 2016, due to the deconsolidation of Asterias.

(3) Includes LifeMap Solutions, Inc., a wholly-owned subsidiary of LifeMap Sciences.

(4) Cell Cure expenses, although shown 100% in the table above, are funded 75% by BioTime and 25% by noncontrolling interests in Cell Cure.

General and administrative expense for the years ended December 31, 2016 and 2015 decreased by $0.7 million. The decrease is mainly attributable to a $2.1 million decrease in stock-based compensation expense due primarily to modification adjustments made in 2015 and lower exercise prices for grants made in 2016. This decrease is offset by an increase in bad debt expense of $0.9 million to account for bad debts on subscription receivables for LifeMap Sciences and shared services receivable from Ascendance. In addition, there was an increase of $0.5 million for payroll and related expenses due to an increase in headcount.

LifeMap Sciences expenses decreased $1.8 million due to reductions of headcount.

OncoCyte expenses increased by $1.6 million due to increased headcount and increased public company compliance and reporting costs.

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.

For the period January 1, 2017 through February 16, 2017, OncoCyte's operating expenses and results will be included in our consolidated operating expenses and results. Beginning on February 17, 2017, with the OncoCyte Deconsolidation, we will no longer include OncoCyte's operating expenses and results with our consolidated operating expenses and results. However, beginning on February 17, 2017, the market value of OncoCyte common stock held by BioTime will be reflected on BioTime's consolidated balance sheet and changes in the market value of those shares will be reflected in BioTime's consolidated statements of operations, included in other income and expenses, net. See Note 16 to our consolidated financial statements.

Other income and expenses, net

Unrealized gain on deconsolidation of Asterias – During the year ended December 31, 2016, we recorded an unrealized gain of $49.0 million in connection with the Asterias Deconsolidation.

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We expect to recognize an unrealized gain on the OncoCyte Deconsolidation which occurred on February 17, 2017, in our consolidated statements of operations for the quarter ending March 31, 2017.

Unrealized gain on Asterias shares – We own 21.7 million shares of common stock of Asterias, or approximately 46% of Asterias outstanding common stock as of December 31, 2016. We elected to account for our shares in Asterias at fair value using the equity method of accounting beginning on May 13, 2016, the date of the Asterias Deconsolidation. Our Asterias shares had a fair value of $100.0 million as of December 31, 2016 and a fair value of $65.7 million as of May 13, 2016, based on the closing price of Asterias common stock on the NYSE MKT on those respective dates, resulting in unrealized gain of $34.3 million recorded in 2016.

Interest income/(expense) – During 2016, we incurred $1.1 million in interest expense which includes $0.3 million in amortized interest expenses from our leasehold improvements and lease liability, offset by $0.3 million of interest income. During 2015, we incurred $0.5 million in interest expense offset by $0.1 million in interest income. Interest income is primarily attributed to interest earned on money market funds during their respective years.

Gain on certain assets – During 2015, a $3.7 million unrealized gain was generated on the sale of a certain group of assets as part of our acquisition of shares of common stock of Ascendance in December 2015.

BioTime's share of losses and impairment in equity method investment in Ascendance – During 2016, we recognized $4.7 million as our share of Ascendance's net loss and from an impairment charge of the remaining carrying value in our Ascendance investment based on a determination that an impairment in the value of the shares had occurred. During 2015, we recognized $35,000 for our share of Ascendance's net loss.

Other income/(expense) – Other income and expenses, net, in 2016 and 2015 consists primarily of net foreign currency transaction gains and losses recognized by ESI and by Cell Cure.

Comparison of Years Ended December 31, 2015 and 2014

Revenues

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

	Year Ended December 31,		$ Increase/ Decrease	% Increase/ Decrease
	2015	2014		
Subscription and advertising	$ 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%

Our subscription and advertising revenues amounted to $1.4 million and $1.2 million for the years ended December 31, 2015 and 2014, respectively. License fee revenue entirely represents 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 in 2015. 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 IIA recognized through Cell Cure. All of the NIH grants expired as of December 31, 2015.

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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 (amounts 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%

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 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 (amounts in thousands).

		Amount[1]		Percent	
Company	Program	2015	2014	2015	2014
Asterias Biotherapeutics	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	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%

(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) Includes LifeMap Solutions, a wholly-owned subsidiary of LifeMap Sciences.

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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's 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 (amounts in thousands).

	Amount(1)		Percent	
Company	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	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 the respective years.

Gain on certain assets – During 2015, a $3.7 million unrealized gain was generated on the sale of a certain group of assets as part of our acquisition of shares of common stock of Ascendance in December 2015.

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

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

Income Taxes

Income Taxes– Although the Asterias Deconsolidation was not a taxable transaction to us and did not result in a tax payment obligation, the $49.0 million gain on the Asterias Deconsolidation recorded by us generated a deferred tax liability that was fully offset by our net operating losses. Subsequent to the Asterias Deconsolidation, an unrealized gain of $34.3 million was recorded on the Asterias shares during the year ended December 31, 2016, which was fully offset by available net operating losses and the corresponding release of BioTime’s valuation allowance on deferred tax assets. Accordingly, we did not record any provision or benefit for income taxes for the year ended December 31, 2016. The deferred tax liability generated by the Asterias shares we hold is expected to continue to be a source of taxable income as prescribed by ASC 740-10-30-17 that will more likely than not result in the realization of our deferred tax assets to the extent of those deferred tax liabilities.

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We have established a full valuation allowance pertaining to our deferred tax assets presented in the consolidated balance sheet as of December 31, 2016 and 2015.

A deferred income tax benefit of $4.5 million was recorded for the year ended December 31, 2015, of which $4.8 million of the benefit was related to federal taxes and $290,000 was related to state taxes. This deferred tax benefit was wholly attributable to Asterias.

Liquidity and Capital Resources

At December 31, 2016, we had $22.1 million of cash and cash equivalents on hand of which $13.6 million was held by subsidiaries, including $10.2 million held by OncoCyte. We also hold Asterias shares valued at approximately $100 million as of December 31, 2016, and OncoCyte shares valued at $71 million as of February 17, 2017, that we may use for liquidity, as necessary and as market conditions allow. BioTime has no present plan to liquidate its holdings of Asterias or OncoCyte shares. The market values shown may not represent the amount that could be realized in a sale of Asterias or OncoCyte shares due to various market and regulatory factors, including trading volume or market depth factors and volume and manner of sale restrictions under Federal securities laws, prevailing market conditions and prices at the time of any sale, and subsequent sales of securities by the subsidiaries.

On February 15, 2017, we raised approximately $18.7 million, after deducting underwriting discounts, commissions and other estimated offering expenses, through the sale of 7,453,704 common shares in an underwritten public offering (the “Offering”).

Since inception, we have incurred significant net losses and have funded our 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, 2016, we had an accumulated deficit of approximately $196 million, working capital of $17 million and shareholders’ equity of $131 million. We have evaluated projected cash flows for us and our subsidiaries and we believe that our cash, cash equivalents, and available for sale securities of $12.5 million (which does not include cash held by OncoCyte due to the OncoCyte Deconsolidation noted above) as of December 31, 2016, and the net proceeds of $18.7 million raised in the Offering, provide sufficient cash, cash equivalents, and working capital to carry out our current operations through at least twelve months from the issuance date of our consolidated financial statements included elsewhere in this Report.

Our projected cash flows are subject to various risks and uncertainties. For example, clinical trials being conducted by Cell Cure will be funded in part with funds from grants and not from cash on hand. If Cell Cure were to lose its grant funding or we are unable to continue to provide working capital to Cell Cure, or both, Cell Cure 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 adequate financing from another source that could be used for its clinical trial. The unavailability or inadequacy of financing to meet future capital needs could force us to modify, curtail, delay, or suspend some or all aspects of our planned operations. Our determination as to when we will seek new financing and the amount of financing that we will need will be based on our evaluation of the progress we make in our research and development programs, any changes to the scope and focus of those programs, and our projection of future costs, revenues, and rates of expenditure. We cannot assure that adequate financing will be available on favorable terms, if at all. Sales of additional equity securities by us or our subsidiaries could result in the dilution of the interests of present shareholders.

Cash used in operating activities

During 2016, our total research and development expenses were $36.1 million and our general and administrative expenditures were $28.4 million. Net income attributable to BioTime for the year ended December 31, 2016 amounted to $33.6 million. Net cash used in operating activities during this period amounted to $42.3 million. The difference

between the net income and net cash used in operating activities during the year ended December 31, 2016 was primarily attributable to the following noncash items: $15.0 million loss attributable to non-controlling interests, gain of $49.0 million related to the Asterias Deconsolidation, unrealized gain of $34.4 million recorded for the increase in fair value of our Asterias shares from May 13, 2016 through December 31, 2016, offset in part by $8 million of stock-based compensation expense recognized for employees, consultants and directors, $3.6 million of amortization of intangible assets, amortization of $1.5 million in deferred grant income, $1.2 million of depreciation expenses, $1.0 million of bad debt expenses from trade and other receivables, including receivables from Ascendance, $3.1 million noncash warrant expense relating to warrants issued to Asterias shareholders in March 2016 and $4.7 million loss on impairment of our Ascendance equity method investment. Changes in working capital impacted our cash used in operations by $0.7 million as a net use of cash.

For the period January 1, 2017 through February 16, 2017, OncoCyte's cash used in operating activities will be included in our consolidated cash used in operations. Beginning on February 17, 2017, due to the OncoCyte Deconsolidation, we will no longer include OncoCyte's cash used in operating activities with our consolidated cash used in operations.

Cash used in investing activities

During the year ended December 31, 2016, $10.9 million was used for investing activities. The primary components of this use of cash were $8.4 million resulting from the deconsolidation of Asterias cash and cash equivalents, and $2.5 million used to purchase property and equipment, including leasehold improvements to our Alameda lease.

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For the period January 1, 2017 through February 16, 2017, OncoCyte's cash used in investing activities will be included in our consolidated cash used in investing activities. Beginning on February 17, 2017, due to the OncoCyte Deconsolidation, we will no longer include OncoCyte's cash used in investing activities with our consolidated cash used in investing activities.

Cash provided by financing activities

During the year ended December 31, 2016, net cash provided by financing activities was approximately $32.8 million. The primary sources of cash provided by financing activities were: net proceeds of $18.6 million from the sale of common shares in an underwritten public offering, $9.8 million in net proceeds from OncoCyte's sale of its common stock and warrants to purchase OncoCyte common stock, $2.2 million in proceeds from exercise of subsidiary stock options principally by Asterias option holders prior to the Asterias Deconsolidation, and $1.8 million in proceeds from the issuance of convertible debt by Cell Cure to its shareholders other than us.

For the period January 1, 2017 through February 16, 2017, OncoCyte's cash flows from financing activities, if any, will be included in our consolidated cash flows from financing activities. Beginning on February 17, 2017, due to the OncoCyte Deconsolidation, we will no longer include OncoCyte's cash flows from financing activities with our consolidated cash flows from financing activities.

Contractual obligations

As of December 31, 2016, our contractual obligations for the next five years and thereafter were as follows (in thousands):

	Payments Due by Period				
Contractual Obligations [1]	Total	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating leases [2]	$6,132	$ 1,098	$ 2,087	$ 1,945	$ 1,002
Capital lease [3]	512	202	310	-	-
Promissory notes	219	99	120	-	-
Convertible debt to noncontrolling shareholders of Cell Cure	2,544	1,076	1,468	-	-
Total	$9,407	$ 2,475	$ 3,985	$ 1,945	$ 1,002

(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, including the lease liability, leases of the offices and laboratory facilities of LifeMap Sciences, Cell Cure and other operating leases of lab equipment. See Note 11 to our consolidated financial statements regarding the lease liability.

(3) Includes capital lease of lab equipment.

Off-Balance Sheet Arrangements

As of December 31, 2016, 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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