

BIOTIME INC  
Form 10-K  
March 14, 2019

**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, 2018

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 (I.R.S. Employer  
incorporation or organization) 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**

<b>Title of each class</b>	<b>Name of exchange on which registered</b>
Common stock, no par value	NYSE American

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

Edgar Filing: BIOTIME INC - Form 10-K

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer  
Non-accelerated filer Smaller reporting company  
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 13(a) of the Exchange Act.

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, 2018 was \$176.7 million. 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 11, 2019 was 149,360,926.

Documents Incorporated by Reference

Edgar Filing: BIOTIME INC - Form 10-K

Portions of the registrant's Proxy Statement for 2019 Annual Meeting of Shareholders to be filed pursuant to Regulation 14A within 120 days of the Registrant's fiscal year ended December 31, 2018 are incorporated by reference in Part III

BioTime, Inc.

Table of Contents

	Page Number
<b><u>Part I.</u></b>	
<b><u>Item 1 - Business</u></b>	2
<b><u>Item 1A Risk Factors</u></b>	24
<b><u>Item 1B Unresolved Staff Comments</u></b>	43
<b><u>Item 2 - Properties</u></b>	43
<b><u>Item 3 - Legal Proceedings</u></b>	43
<b><u>Item 4 - Mine Safety Disclosures</u></b>	43
<b><u>Part II.</u></b>	
<b><u>Item 5 - Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities</u></b>	44
<b><u>Item 6 - Selected Financial Data</u></b>	44
<b><u>Item 7 - Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></b>	45
<b><u>Item 7A - Quantitative and Qualitative Disclosures about Market Risk</u></b>	57
<b><u>Item 8 - Financial Statements and Supplementary Data</u></b>	58
<b><u>Item 9 - Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u></b>	101
<b><u>Item 9A- Controls and Procedures</u></b>	101
<b><u>Item 9B Other Information</u></b>	102
<b><u>Part III.</u></b>	
<b><u>Item 10- Directors, Executive Officers, and Corporate Governance</u></b>	102

<b><u>Item 11- Executive Compensation</u></b>	<b>102</b>
<b><u>Item 12- Security Ownership of Certain Beneficial Owners and Management, and Related Stockholder Matters</u></b>	<b>102</b>
<b><u>Item 13- Certain Relationships and Related Transactions, and Director Independence</u></b>	<b>102</b>
<b><u>Item 14- Principal Accounting Fees and Services</u></b>	<b>102</b>
<b><u>Part IV</u></b>	
<b><u>Item 15 - Exhibits, Financial Statement Schedules</u></b>	<b>103</b>
<b><u>Item 16 - Form 10-K Summary</u></b>	<b>105</b>
<b><u>Signatures</u></b>	<b>106</b>

## PART I

This Annual Report on Form 10-K (“Report”) contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

our plans to research, develop and commercialize our product candidates;

the initiation, progress, success, cost and timing of our clinical trials and product development activities;

the therapeutic potential of our product candidates, and the disease indications for which we intend to develop our product candidates;

our ability and timing to advance our product candidates into, and to successfully initiate, conduct, enroll and complete, clinical trials;

our ability to manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;

the performance of third parties in connection with the development and manufacture of our product candidates, including third parties conducting our clinical trials as well as third-party suppliers and manufacturers;

the potential of our cell therapy platform, and our plans to apply our platform to research, develop and commercialize our product candidates;

our ability to obtain funding for our operations, including funding necessary to initiate and complete clinical trials of our product candidates;

the size and growth of the potential markets for our product candidates and our ability to serve those markets;

the potential scope and value of our intellectual property rights;

our ability, and the ability of our licensors, to obtain, maintain, defend and enforce intellectual property rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing the proprietary rights of third parties;

our ability to recruit and retain key personnel;

our ability to successfully integrate the operations of Asterias into BioTime; and

other risks and uncertainties, including those described under Part I, Item 1A. Risk Factors of this Report.

Any forward-looking statements in this Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A. Risk Factors and elsewhere in this Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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

The description or discussion, in this Report, 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 Report contains market data and industry forecasts 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 Report 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 several assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions, and estimates.

## ITEM 1. BUSINESS

### Overview

BioTime is a clinical-stage biotechnology company developing new cellular therapies for degenerative retinal diseases, neurological conditions associated with demyelination, and aiding the body in detecting and combating cancer. Our programs are based on our proprietary cell-based therapy platform and associated development and manufacturing capabilities. With our platform we develop and manufacture specialized, terminally-differentiated human cells from our pluripotent and progenitor cell starting materials. These differentiated cells are developed either to replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury, or are administered as a means of helping the body mount an effective immune response to cancer.

### *Product Candidates & Other Programs*

We have three cell therapy programs in clinical development:

*OpRegen*<sup>®</sup>, a retinal pigment epithelium cell replacement therapy currently in a Phase I/IIa multicenter clinical trial for the treatment of advanced dry age-related macular degeneration (“dry-AMD”) with geographic atrophy (“OpRegen

trial”). Dry-AMD accounts for approximately 85-90% of all age-related macular degeneration cases and is the leading cause of blindness in people over the age of 60. There currently are no therapies approved by the U.S. Food and Drug Administration (“FDA”) for dry-AMD.

*OPC1*, an oligodendrocyte progenitor cell therapy currently in a Phase I/IIa multicenter clinical trial for acute spinal cord injuries. This clinical trial has been partially funded by the California Institute for Regenerative Medicine (“CIRM”).

*VAC2*, an allogeneic (non-patient-specific or “off-the-shelf”) cancer immunotherapy of antigen-presenting dendritic cells currently in a Phase I clinical trial in non-small cell lung cancer. This clinical trial is being funded and conducted by Cancer Research UK, the world’s largest independent cancer research charity.

We also have cell/drug delivery programs based upon our proprietary *HyStem*<sup>®</sup> cell and drug delivery matrix technology. *HyStem* was designed to support the formulation, transfer, retention, and engraftment of cellular therapies. We also established and support multiple collaborations with both academic and for-profit partners to develop *HyStem* for additional therapeutic uses, and we sell both research and GMP-grade *HyStem* to support additional external research and development activities.

Our lead cell delivery clinical program is *Renovia*<sup>®</sup>, a medical device developed as a replacement for whole adipose tissue in cell assisted lipotransfer (CAL) procedures, and which met its primary endpoint of change in hemifacial volume at 6 months in the treated patients compared to patients in the delayed treatment arm as measured by three-dimensional photographic volumetric assessment, in a European pivotal clinical trial in patients with HIV-associated facial lipoatrophy. In 2018, we submitted a design dossier for EU market clearance (CE Mark) for the use of *Renovia* as a device to aid in transferring a patient’s own adipose tissue to treat certain forms of facial lipoatrophy, or fat loss. We have ongoing discussions with our European notified body and are currently awaiting notification as to its status. We expect to receive a decision from the notified body in the second half of 2019.

### *Ownership in Other Companies*

In addition to seeking to create value for shareholders by developing product candidates and other technologies through our clinical development programs, we also seek to create value from our technologies through partnering and strategic transactions. Two publicly-traded companies, OncoCyte Corporation (“OncoCyte”, NYSE American: OCX) and AgeX Therapeutics, Inc. (“AgeX”, NYSE American: AGE) were founded by BioTime in order to develop products from technologies invented within BioTime. Both companies subsequently raised capital and we distributed a portion of our shares in each company to our shareholders. A portion of AgeX common stock was also sold to Juvenescence Limited (“Juvenescence”) in exchange for \$21.6 million of cash and a \$21.6 million convertible promissory note.

Currently, our largest equity holding (approximately 28%) is in OncoCyte which we formed in 2015 to continue development of cancer diagnostic technology, and which is now focused on developing confirmatory diagnostic tests for lung cancer utilizing novel liquid biopsy technology. In late January 2019, OncoCyte announced successful results of its DetermaVu R&D validation study. OncoCyte announced in February 2019 that it had raised \$40.25 million in gross proceeds in a public offering of its common stock. See “—Recent Transactions Affecting Our Corporate Organization,” below.

We also have a minority equity holding (approximately 4.8%) in AgeX Therapeutics, Inc., which we formed in 2017 to continue development of certain early-stage programs relating to cell immortality, regenerative biology, aging, and age-related diseases. AgeX had been our consolidated subsidiary until its deconsolidation August 30, 2018. See “—Recent Transactions Affecting Our Corporate Organization,” below. AgeX’s initial programs focus on utilizing brown adipose tissue to target diabetes, obesity, and heart disease, and induced tissue regeneration technology utilizing the human body’s own abilities to scarlessly regenerate tissues damaged from age or trauma.

We also continue to hold the \$21.6 million convertible promissory note issued by Juvenescence.

The combined value of these holdings as of March 13, 2019, was \$85.5 million. The value of the Juvenescence note is based on the principal amount of \$21.6 million plus accrued interest. The values of OncoCyte and AgeX are based on the closing price of their common stock on that date. See “ITEM 1A. RISK FACTORS—Risks Related to Our Business Operations and Capital Requirements—The value of our investments in other companies fluctuates based on their respective stock prices and could be negatively impacted by poor business performance,” below. Though our principal focus is on advancing our three cell therapy programs in clinical development, we may seek to create additional value through corporate transactions, as we have in the past. Our securities holdings also may be a significant source of capital to fund our operations as an alternative to issuing additional BioTime securities.

### *Corporate Information*

BioTime is incorporated in the State of California. Our common stock trades on the NYSE American and the Tel Aviv Stock Exchange under the symbol “BTX.” Our principal executive offices are 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.biotime.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”).

## **Recent Transactions Affecting Our Corporate Organization**

### *Asterias Merger*

On March 8, 2019, we acquired Asterias Biotherapeutics, Inc. (“Asterias”) via merger. In the acquisition, each outstanding share of Asterias common stock was converted into our common stock at an exchange ratio of 0.71 BioTime shares for each Asterias share.

Prior to May 13, 2016, Asterias was a majority-owned and consolidated subsidiary of BioTime. On May 13, 2016, BioTime’s percentage ownership decreased from 57.1% to 48.7% as a result of the sale of shares of common stock by Asterias in a public offering, resulting in BioTime’s loss of control of Asterias under generally accepted accounting principles in the U.S. (“GAAP”). Accordingly, BioTime deconsolidated Asterias effective May 13, 2016. From May 13, 2016 until the consummation of the merger on March 8, 2019, BioTime accounted for its ownership of Asterias under the equity method of accounting, electing the fair value option, with the investment carried on the consolidated balance sheet at fair value and all subsequent changes in fair value included in BioTime’s consolidated statements of operations in other income and expenses, net. The deconsolidation of Asterias is sometimes referred to as the “Asterias Deconsolidation” in this Report.

Audited financial statements of Asterias for the years ended December 31, 2018 and 2017 are included as financial statement schedules in Part IV, Item 15, and are filed as an exhibit to this Report.

### *AgeX Deconsolidation and Distribution*

On August 30, 2018, we entered into a Stock Purchase Agreement with Juvenescence and AgeX, under which we sold 14,400,000 of our shares of AgeX common stock to Juvenescence for \$3.00 per share. The transaction resulted in over \$43 million in non-dilutive financing for BioTime.

Upon completion of that transaction, our percentage ownership of AgeX's outstanding shares of common stock decreased from 80.4% to 40.2%, and Juvenescence's percentage ownership increased from 5.6% to 45.8%. As a result of the transaction, as of August 30, 2018, AgeX was no longer our subsidiary and effective that date, we deconsolidated AgeX's consolidated financial statements and consolidated results of operations from BioTime's under GAAP due to the decrease in our percentage ownership in AgeX to below 50%. Prior to that date, AgeX was our majority-owned and consolidated subsidiary. Beginning on August 30, 2018 through November 28, 2018 (the date on which AgeX began trading as a public company as discussed below), we accounted for AgeX using the equity method of accounting, electing the fair value option, recording the retained interest in AgeX at fair value on August 30, 2018 with all subsequent changes in fair value included in our consolidated statements of operations in other income and expenses, net.

On November 28, 2018, AgeX began trading as a public company on the NYSE American (under the symbol "AGE") and, on that date, we distributed 12.7 million shares of AgeX common stock we owned to our shareholders, on a pro rata basis, in the ratio of one share of AgeX common stock for every 10 shares of our common stock they owned. This distribution was accounted for at fair value as a taxable, dividend-in-kind transaction in the aggregate amount of \$34.4 million. Immediately following the distribution, we owned 1.7 million shares of AgeX common stock, all of which we still own, and which represents approximately 4.8% of AgeX's outstanding common stock as of December 31, 2018. We hold the shares of AgeX common stock that we own as marketable equity securities.

As of, and for each reporting period after August 30, 2018, the fair value of our ownership interest in AgeX will be determined by multiplying the fair value of a share of AgeX common stock by the number of such shares we own.

AgeX's consolidated assets and liabilities are not included in our audited consolidated balance sheet at December 31, 2018, due to the deconsolidation. The fair value of the AgeX shares we owned is shown on our audited consolidated balance sheet as of December 31, 2018. Our consolidated balance sheet at December 31, 2017 includes AgeX's consolidated assets and liabilities, after intercompany eliminations. Our audited consolidated statements of operations for the year ended December 31, 2018 include AgeX's consolidated results for the period through August 29, 2018, the day immediately preceding the deconsolidation. For the year ended December 31, 2017, our consolidated results include AgeX's consolidated results.

The deconsolidation of AgeX is sometimes referred to as the "AgeX Deconsolidation" in this Report.

The distribution of AgeX common stock is sometimes referred to as the "AgeX Distribution" in this Report.

Audited consolidated financial statements of AgeX for the years ended December 31, 2018 and 2017 will be included as financial statement schedules in Part IV, Item 15 and will be filed as an exhibit by an amendment to this Report.

#### *OncoCyte Deconsolidation*

Effective February 17, 2017, we deconsolidated the financial statements and results of operations of OncoCyte under GAAP due to the decrease in our percentage ownership in OncoCyte to below 50% as a result of OncoCyte's issuance of 625,000 shares of its common stock upon exercise of warrants. Prior to that date, OncoCyte was our majority-owned and consolidated subsidiary. Since February 17, 2017, we have accounted for OncoCyte using the equity method of accounting, electing the fair value option, with all subsequent changes in fair value included in our consolidated statements of operations in other income and expenses, net. As of, and for each reporting period after February 17, 2017, the fair value of our ownership interest in OncoCyte has been determined by multiplying the closing price of OncoCyte common stock as quoted on NYSE American by the number of such shares we owned.

OncoCyte's assets and liabilities are not included in our audited consolidated balance sheet at December 31, 2017 due to the deconsolidation. The fair value of OncoCyte shares we owned is shown on our audited consolidated balance sheet as of December 31, 2018 and 2017. Our audited consolidated statements of operations for the year ended December 31, 2017 include OncoCyte's results from January 1, 2017 through February 16, 2017, the day immediately preceding the deconsolidation. OncoCyte's results are not included in our audited consolidated statements of

operations for the year ended December 31, 2018.

The deconsolidation of OncoCyte is sometimes referred to as the “OncoCyte Deconsolidation” in this Report.

Audited financial statements of Onco Cyte for the years ended December 31, 2018 and 2017 will be included as financial statement schedules in Part IV, Item 15 and will be filed as an exhibit by an amendment to this Report.

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.

### **2018 and Early 2019 Highlights**

We achieved numerous strategic accomplishments during 2018 and early 2019, including advancing clinical trials and product development in several key programs.

We presented encouraging data from the OpRegen trial in dry-AMD. Data from the ongoing open-label dose escalation trial was presented in May 2018 at the Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO) in Honolulu, Hawaii by Eyal Banin, MD, PhD. Data presented from the phase I/IIa open-label study showed that both the surgical procedure and the OpRegen cells were generally well tolerated, with no treatment-related systemic SAEs reported to date in the first nine patients. The Best Corrected Visual Acuity (BCVA) of these patients remained relatively stable. In addition, the imaging of patients 8 and 9 suggested early signs of structural improvement within the retina.

OpRegen trial in dry-AMD expanded. We expanded the OpRegen trial in dry-AMD in the U.S. with the opening of two additional sites in California; the Byers Eye Institute at the Stanford University School of Medicine and The Retinal Consultants Medical Group in Sacramento.

We completed enrollment of Cohort 3 in the OpRegen trial in dry-AMD and received Data and Safety Monitoring Board (DSMB) approval to move forward with better sighted patients in Cohort 4 (20/64 to 20/250 with smaller areas of GA) and treated the first 3 subjects. Having demonstrated that OpRegen was well tolerated in legally blind patients, we believe that moving to earlier stages of disease may be more likely to demonstrate evidence of clinical benefit as assessed by improved BCVA, reading speed, visual acuity in low luminance, and microperimetry.

Supporting this hypothesis, the visual acuity of the first 3 Cohort 4 patients have all seen improvements from baseline levels, which will need to be followed for longer periods of time, and preliminary evidence of improved structural changes following treatment have been observed.

In January 2019, we entered into a research and option agreement with Orbit Biomedical for the assessment of their 510k cleared Subretinal Delivery System in our ongoing OpRegen trial. The Orbit device is designed to precisely and consistently deliver therapeutics to the sub-retinal space via a suprachoroidal route, avoiding the need for a vitrectomy and perforation of the retina. We currently plan to introduce the Orbit device into our Phase I/IIa clinical study in the second quarter of 2019 and we intend to dose at least six patients with the device.

In August 2018, we sold 50% of our equity position in AgeX for \$43.2 million to Juvenescence. We received \$21.6 million in cash and the remaining \$21.6 million was paid in the form of a 2-year convertible promissory note with an annual interest rate of 7%, payable at maturity in August 2020. If Juvenescence conducts an initial public offering, the note is convertible into Juvenescence stock which includes an upward adjustment if the price of AGE is above \$3.00 at the time of the Juvenescence public offering.

In November 2018, AgeX began trading as a public company and we distributed 88% of our equity position in AgeX to our shareholders. Immediately following the distribution, we owned 1.7 million shares of AgeX common stock, all of which we still own, and which represents approximately 4.8% of AgeX's outstanding common stock as of December 31, 2018 and which shares we hold as marketable equity securities.

On March 8, 2019, we acquired Asterias. We entered into an Agreement and Plan of Merger with Asterias on November 7, 2018 and closed the acquisition on March 8, 2019. As a result of this acquisition, we acquired several cell replacement product candidates and now have three in active clinical development: OpRegen, OPC1 and VAC2. We expect to achieve significant cost synergies as we complete the integration of Asterias into BioTime.

In 2018, Cell Cure was awarded a grant of up to 6.9 million Israeli New Shekels (approximately \$1.9 million) from the Israel Innovation Authority (IIA). The grant provides funding for the continued development of OpRegen, and to date the IIA has provided annual grants to Cell Cure totaling approximately \$13 million.

We established an innovative cell therapy manufacturing facility in the Bio Park on the campus of the Hadassah University Hospital in Jerusalem, Israel. The facility includes process development laboratories and an 800 square meter (8,600 square feet), state-of-the-art, cGMP manufacturing facility. It is designed and equipped to enable simultaneous GMP processes and to produce OpRegen and a range of cell therapy products for human use in clinical trials as well as at a scale suitable for commercial launch.

During 2018, we were issued 17 new patents. These new patents add to the over 800 issued patents or pending patent applications we own or license worldwide and address many of our key programs.



## **Business Strategy**

Our goal is to become a leading cell therapy company developing differentiated pluripotent cells into specific cell types for use as whole cell treatments to restore diseased or diminished functions, such as impaired vision, loss of movement and sensation, or to increase immune response to tumors. Significant near-term activities that underlie our business strategy include:

*Complete the integration of Asterias into BioTime.* On March 8, 2019, we completed our acquisition of Asterias. Over the next few months, we plan to integrate clinical and manufacturing related activities surrounding OPC1 and VAC 2 into our business. We expect to significantly reduce the cash burn of the combined companies by eliminating redundant personnel and utilizing the expertise of existing staff at BioTime to advance the clinical development of OPC1 and VAC2.

*Complete enrollment in the Phase I/IIa study of OpRegen.* In January 2019, we announced an exclusive partnership with Orbit Biomedical to assess its vitrectomy-free subretinal injection device as a means of delivering OpRegen in our ongoing OpRegen Phase I/IIa clinical study. We are in the process of amending the clinical protocol for that study to incorporate the Orbit device alongside our new and more user-friendly thaw and inject (“TAI”) formulation into that study and intend to dose at least six of our remaining patients with the Orbit device. We expect to complete enrollment in the study by the end of 2019.

*Advance clinical development of OPC1.* In January 2019, Asterias announced 12-month data on 25 patients in its Phase I/IIa trial in SCI. These data were supportive of further clinical development of OPC1. During 2019, we plan to further analyze these results and meet with the FDA to discuss next steps in the clinical development of OPC1.

*Advance clinical development of VAC2.* In coordination with Cancer Research UK, we will continue to advance the clinical development of VAC2 with additional patient exposures in a Phase 1 clinical trial in non-small cell lung cancer.

*Create value through our OncoCyte, AgeX, and Juvenescence assets.* The combined market value of these assets was approximately \$85.5 million as of March 13, 2019. We will continue to evaluate how and when some or all of these assets may be converted into cash or other forms of value in 2019.

## **Cell Therapy Technology**

We believe we are a leader in pluripotent cell asset development and lineage derivation protocols. Pluripotent cells, which are widely published as capable of becoming any human cell type, have potential applications in many areas of medicine with large unmet patient needs, including certain age-related degenerative diseases and degenerative conditions for which there presently are no cures. We currently are focused on developing pluripotent cells into three specific cell types: retinal pigment epithelial cells, oligodendritic progenitor cells and dendritic cells.

## **Pluripotent Stem Cells**

Unlike pharmaceuticals that require a molecular target, cellular therapies are often aimed at regenerating or replacing affected cells and tissues and/or improving bodily functions such as immune surveillance, and therefore, may have broader or more suitable applicability than many pharmaceutical products. Small molecules and biologic therapies that require systemic delivery into the body often have unexpected results, or side effects, that can limit their usefulness. Cell replacement is locally administered, so systemic side effects are usually not a primary concern in therapeutic development. The risk profile more closely resembles that of transplant medicine, focused more on whether the transplanted cells are rejected by the body and whether the cells function as expected. We currently are using our pluripotent stem cells as biological starting material from which we derive three separate and specific cell types, each of which are product candidates currently in clinical testing.



## Cell Therapy Product Candidates

### OpRegen

OpRegen is our lead ophthalmic product candidate (currently in a Phase I/IIa clinical trial) for the treatment of advanced dry-AMD (age-related macular degeneration) with geographic atrophy (GA). AMD is a gradual, progressive, deterioration of the macula, the small sensitive area in the center of the retina that provides clear, high definition central vision. AMD affects over 30 million people worldwide and approximately 1.6 million people are diagnosed annually in the U.S. It is the leading cause of vision loss in people over the age of 60 in the developed world. Once the atrophy involves the fovea (the center of the macula), patients lose their central vision, making facial recognition, reading and driving difficult or impossible, and potentially resulting in legal blindness. Its cause is unknown, but thought to be multifactorial (e.g. genetics, environmental influences, age). There are two forms of AMD, the dry form and the wet form. Dry-AMD typically advances slowly toward GA in which retinal pigment epithelial (RPE) cells and photoreceptors deteriorate over time. RPE cells support and nourish the retina. Approximately 85-90% of AMD patients suffer from dry-AMD, for which there is no FDA-approved medical therapies. Dry-AMD may also lead to wet-AMD, a condition for which there are FDA-approved treatments, but these treatments have not been approved for the treatment of dry-AMD. Physicians often recommend a healthy diet, exercise, and/or nutritional supplements for dry-AMD, but nutritional supplements have shown limited efficacy in delaying the onset of more progressive disease in longer-term studies.

We believe one of the most promising future therapies for dry-AMD is to replace the layer of damaged RPE cells. OpRegen is a cell replacement therapy derived from our pluripotent cell technology. Using a proprietary directed differentiation method, OpRegen is a formulation of animal-free RPE cells with high yield and purity that can be transplanted directly into the patient's eye, where the patient's own RPE cells are missing or dysfunctional. The OpRegen therapeutic approach is designed to replace damaged or lost RPE cells with the goal of slowing disease progression to preserve and/or restore visual function.

Preclinical studies in the Royal College of Surgeons (RCS) rat have shown that following a single subretinal injection, OpRegen as a suspension of cells rapidly organized into their natural monolayer structure and survived until the end of the study, which we believe is critical to the potential success of OpRegen in humans. Additionally, rats receiving OpRegen had objective evidence of improved optomotor tracking, indicating functional visual improvement compared to control animals.

OpRegen is intended to be an allogeneic, “off-the-shelf,” product provided to retinal surgeons in an “easy-to-use” form for transplantation. Unlike other investigational treatments for dry-AMD, and currently-marketed treatments for wet-AMD (Ranibizumab (Lucentis<sup>®</sup>) and Aflibercept (Eylea<sup>®</sup>)), that require multiple, frequent injections into the eye, we expect OpRegen would potentially be administered in a single procedure, or once every several years.

The patients in our ongoing Phase I/IIa clinical study are 50 years of age or older, whose dry-AMD has advanced to the GA stage, with absence of additional concomitant ocular disorders. The eye in which the disease has progressed the most is treated, while the other eye serves as a control. Following injection, the patients are followed for 12 months at specified intervals to evaluate the safety and tolerability of OpRegen.

Following the initial 12-month period, patients are evaluated at longer intervals for up to an additional five years following administration. A secondary objective of the clinical trial is 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, several vision tests are used to quantify stabilization or improvements in visual function. We also perform anatomical evaluation imaging to assess the restoration of the structure of the retina.

Interim data from the first 12 subjects in Cohorts 1-3 of our ongoing Phase I/IIa clinical study have been encouraging and suggest that OpRegen RPE cells are generally well-tolerated when administered by subretinal injection in these legally blind patients with large areas of GA that have encompassed the foveal area. The surgical procedures were generally well-tolerated, with spectral domain optical coherence tomography (SD-OCT) images showing absorption of the subretinal fluid in the bleb less than 48 hours after surgery and healing of the site of retinal penetration by the cannula within a few weeks. Initial findings using a variety of imaging modalities suggest presence of cells in the subretinal space, an observation consistent with, and supported by, the data from preclinical studies of OpRegen. Findings on clinical examination by different imaging modalities show potential improvements in retinal structure, which could precede visual functional improvements. Though it is not definitively known at this time whether these changes represent engraftment and survival of the transplanted cells, data from the preclinical animal studies suggest this is the most likely scenario. Best corrected visual acuity (BCVA) has remained relatively stable in both the treated and non-treated eyes of these advanced AMD patients over the course of the study to date.

Importantly, in this safety-focused study, no unexpected ocular adverse events (AEs) have been observed and those events expected to occur based on the procedures involved in OpRegen administration, such as vitrectomy, have been mild in severity. The majority of these subjects had pre-existing epiretinal membranes (ERMs) at the time of study enrollment and several have experienced new or worsening ERM following the surgical procedure and OpRegen injection and these subjects are being monitored during study follow-up. One instance of retinal detachment occurred in a patient who was legally blind prior to treatment. The event was not assigned as related to treatment, procedure, or to the combination. The patient continued in the study following successful surgical repair. The independent data safety monitoring board (DSMB) approved moving to the fourth cohort based on the safety data from the first three cohorts. Cohort 4 incorporates an additional variety of objective and subjective assessments to look for signs of potential efficacy as well as potential anatomical changes indicative of OpRegen cell function following implantation.

Many of the AEs observed in subretinal procedures are related to the delivery technique utilized during the surgery. In January 2019, we announced an exclusive partnership with Orbit Biomedical to assess their FDA-cleared Orbit Subretinal Delivery System, a vitrectomy-free delivery device for administration of OpRegen within the ongoing clinical study. The device allows for access to the subretinal space via a suprachoroidal approach without creating a hole in the retina and compromising its structural integrity. We believe that the use of this device could significantly decrease the number of AEs and improve dose control of cells in our clinical trials.

We completed enrollment in the first three cohorts of the trial (twelve patients) in the middle of 2018. We began enrollment of Cohort 4 shortly thereafter and have treated three patients to date. We are in the process of amending our clinical protocol to incorporate the Orbit device and our new thaw and inject (TAI) formulation into our Phase I/IIa clinical trial, and we intend to dose at least six patients with the Orbit device. We plan to enroll additional subjects for Cohort 4 at three currently participating sites in the United States. These sites are: Retina-Vitreous Associates in Los Angeles, Retinal Consultants Medical Group in Sacramento and West Coast Retina Medical Group in San Francisco.

We have established an innovative cell therapy manufacturing facility in the Jerusalem Bio Park on the campus of Hadassah University Hospital in Jerusalem, Israel. Our facility is equipped to produce cGMP-grade OpRegen and a range of other cell therapy products for human use in clinical trials as well as at a scale suitable for commercial introduction.

## OPC1

OPC1 is our lead product candidate for the treatment of acute spinal cord injury (“SCI”). SCI occurs when the spinal cord is subjected to a severe crush or contusion injury, such as that caused by a car or motorcycle accident and typically results in severe functional impairment, including limb paralysis, aberrant pain signaling, and loss of bladder and sexual function. There are approximately 18,000 new spinal cord injuries annually in the U.S. (NSCIC SCI Facts and Figures at a Glance (2019)), and there are currently no FDA-approved drugs specifically for the treatment of SCI, although methylprednisolone, a corticosteroid generally used as an anti-inflammatory drug, is sometimes prescribed on an off-label basis to reduce acute inflammation in the injured spinal cord immediately after injury. It is believed that to effect substantial benefit in treating this complex injury, multiple mechanisms of action are required, such as introduction of biologics that preserve surviving neurons and stimulate new nerve axon outgrowth, suppression of lesion formation at the injury site, generation of new blood vessels to repair the ischemic damage from injury, and myelination of the demyelinated and newly formed nerve axons. A key therapeutic target in SCI is replacement of oligodendrocytes that are selectively lost at the injury site. As the sole source of the insulating protein myelin in the brain and spinal cord, oligodendrocytes wrap around nerve axons and allow conduction of electrical impulses throughout the central nervous system (“CNS”). Just as the gain of cognitive and motor functions early in life reflects the progression of connectivity and myelination within the developing CNS, the functional impairments that can occur after a traumatic injury such as SCI are a direct result of severed connections and demyelination.

OPC1 is an oligodendrocyte progenitor cell therapy derived from our pluripotent cell technology under Current Good Manufacturing Practice (cGMP) conditions using a directed differentiation method. These cells are stored frozen until ready for use as direct administration into the injured spinal cord. Based on preclinical studies, when OPC1 is transplanted into the injured spinal cord, the cells undergo further maturation to generate a replacement population of oligodendrocytes at the injury site that are capable of remyelinating denuded and newly formed nerve axons. Prior to their maturation, the transplanted oligodendrocyte progenitor cells stimulate additional reparative processes, including promotion of neuron survival and nerve axon outgrowth, and induction of blood vessel formation in and around the injury site. In addition, OPC1 cells rapidly migrate from the injection point to the injury site where they generate a supportive tissue matrix and suppress the formation of a lesion cavity. Based on the multiple reparative properties associated with OPC1, we believe this candidate cell therapy product is ideally suited to treat neurological conditions such as SCI and other demyelination and demyelination disorders of the CNS.

Under a grant for clinical development, the development of OPC1 has been supported by \$14.3 million in funds from the California Institute for Regenerative Medicine (“CIRM”) from 2014 to date. We intend to apply for additional grants from CIRM for the program’s continued development.

OPC1 has been tested in two clinical trials to date: a five patient Phase I safety trial and a 25 patient Phase I/IIa dose escalation trial (the “SCiStar trial”). The SCiStar trial was conducted at 9 sites in the United States.

In January 2019, Asterias (our now wholly owned subsidiary) announced the following 12-month data from the SCiStar trial:

*Positive Safety Profile* - MRI scans at 12 months post-injection of OPC1 showed no evidence of adverse changes in any of the 25 SCiStar subjects treated with OPC1. Subjects were followed for as long as eight years. To date, there have been no unexpected serious adverse events (SAEs) related to the OPC1 cells.

*Cell Engraftment* - All three SCiStar subjects in Cohort 1 and 95% (21/22) of SCiStar subjects in Cohorts 2 through 5 have magnetic resonance imaging (MRI) scans at 12 months consistent with the formation of a tissue matrix at the injury site, which is encouraging evidence that OPC1 cells engrafted at the injury site and helped to prevent cavitation. Clinically, cavitation is a destructive process that occurs within the spinal cord following spinal cord injuries, and typically results in permanent loss of motor and sensory function. A patient with cavitation can develop a condition known as syringomyelia, which results in additional neurological and functional damage and often results in chronic pain.



*Improved Motor Function* - At 12 months, 95% (21/22) of SCiStar study subjects who were administered either 10 million or 20 million cells of OPC1 (Cohorts 2 through 5) recovered at least one motor level on at least one side. At 12 months, 32% (7/22) of these subjects recovered two or more motor levels on at least one side. At 12 months, the average improvement in upper extremity motor score for these subjects was 8.9 points as measured by the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) scale. No subjects saw decreased motor function following administration of OPC1 and subjects consistently retained the motor function recovery seen through 6 months or saw further motor function recovery from 6 to 12 months.

*Results Excluding Certain SCiStar Study Subjects* - Excluding those SCiStar subjects in Cohorts 2 through 5 that either (i) would not meet the eligibility criteria Asterias proposed to the FDA during its Type B meeting to discuss the next study for OPC1 or (ii) did not receive a modified post-surgical procedure to reduce potential cord compression issues, at 12 months 100% (17/17) of the SCiStar study subjects recovered at least one motor level on at least one side, 41% (7/17) of these subjects recovered two or more motor levels on at least one side, and the average improvement in upper extremity motor score as measured by the ISNCSCI scale for these subjects was 10.2 points.

The FDA designated OPC1 as a Regenerative Medicine Advanced Therapy (“RMAT”) for the treatment of acute SCI and granted it Orphan Drug Designation, which includes the ability for increased interfacing with the FDA during clinical development.

We intend to transfer all cGMP manufacturing processes, including the establishment of H1 cell banks and the OPC1 process development and manufacturing for clinical studies, to our cell therapy manufacturing facility in Jerusalem, Israel where OpRegen process development and production are currently ongoing.

Asterias management had a Type B meeting with the FDA to discuss the next clinical trial of OPC1. We are now analyzing the data from the SCiStar trial to inform us as to how to proceed with further discussions with the FDA. Additionally, we are leveraging our manufacturing capabilities and process development expertise learned from OpRegen to support OPC1’s development.

Because OPC1 has been shown to promote CNS repair through multiple reparative mechanisms, we believe its therapeutic benefit extends beyond SCI to other types of neurological injury and disease, particularly those that involve demyelination. Through ongoing collaborations with academic researchers, OPC1 is currently in preclinical development as treatment for both ischemic stroke and multiple sclerosis, two additional neurological conditions with demyelination as a key component of their pathology. In both cases, the preclinical data generated thus far has provided initial proof of concept efficacy of OPC1, which we intend to use to seek funding for consideration of further preclinical development.

VAC2

VAC2 is our lead product candidate for the treatment of cancer. Cancer afflicts millions worldwide and is one of the largest unmet clinical needs with current treatment options providing limited efficacy and a wide range of debilitating side effects. To provide a more effective and targeted treatment, we are developing VAC2 as an allogeneic, or non-patient specific, cancer vaccine candidate designed to stimulate patient immune responses to telomerase which is commonly expressed in cancerous cells but not in normal adult cells. VAC2, which is produced from our pluripotent cell technology using a directed differentiation method, is comprised of a population of mature dendritic cells. As the most potent type of antigen presenting cell in the body, dendritic cells instruct our body's immune system to attack and eliminate harmful pathogens and unwanted cells. To target cancerous cells, VAC2 is engineered to express the tumor-selective antigen telomerase, which is found in over 85% of all cancers. Because the tumor antigen is loaded exogenously into the dendritic cells prior to administration, VAC2 is a platform technology that can be modified to carry any antigen, including patient-specific tumor neo-antigens. Using pluripotent cells as the starting material for VAC2 production adds several additional advantages to this candidate therapeutic. Compared to technologies that rely on the use of a patient's own blood, our pluripotent cell technology provides a scalable system for production of a large number of vaccine doses in a single lot, lower manufacturing costs, greater product consistency, and off-the-shelf availability to provide broader access to patients. In addition, we believe that as an allogeneic therapy, VAC2 has the potential to stimulate a more robust immune response through an adjuvant effect resulting from the partial immune mismatch between the VAC2 cells and patients receiving the therapy.

In September 2014, Asterias initiated clinical development of VAC2 by entering 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, under which CRUK agreed to fund Phase I clinical development of VAC2 in non-small cell lung cancer. CRUK is responsible, at its own cost, for manufacturing clinical grade VAC2 and for carrying out the Phase I clinical trial of VAC2. Patient enrollment began in June 2018 and four patients have been enrolled to date.

Upon completion of the Phase I clinical trial, we will have an exclusive option to acquire the data generated in the trial and conduct further development of VAC2. The reacquisition fee is approximately \$1.6 million with additional milestone fees based upon initiation of a Phase III study and the filing for regulatory approval, as well as mid-single-digit royalty payments on sales of commercial products. If BioTime declines this option, CRUK will then have an option to obtain a license to BioTime's intellectual property to continue the development and commercialization of VAC2 and related products in exchange to BioTime for a revenue share of development and partnering proceeds. In connection with the CRUK Agreement, we sublicensed to CRUK for use in the clinical trials and product manufacturing process certain patents we licensed or sublicensed to third parties. We will also be obligated to pay to those licensors and sublicensors upon the achievement of various milestones and to pay royalties on sales of products if VAC2 is successfully developed and commercialized.

The allogenic VAC2 program was preceded by the autologous VAC1 program which isolated dendritic cells from a patient's own blood, modified those cells to stimulate immune responses to telomerase and then administered those cells back to the patient as a therapeutic modality. VAC1 was studied for the treatment of Acute Myeloid Leukemia ("AML"), the most common form of acute leukemia in adults. A Phase II clinical trial of VAC1 demonstrated that it successfully manufactured and released in 24 out of the 33 patients enrolled in the study. Twenty-one patients received VAC1 in the study, including 19 in clinical remission and two in early relapse. VAC1 was found to have a favorable safety and tolerability profile. Asterias performed follow-up data collection on the 19 patients treated while in complete remission to determine the long-term effects of the VAC1 administration on remission duration and disease-free survival.

VAC1 utilized an autologous approach where the cellular vaccine needs to be created specifically for each patient. This results in a longer time to administer the therapy as compared to the allogeneic approach of the VAC2 program which is disadvantageous in advanced cancer patients given the rapidity of disease progression. The VAC1 program serves as an effective and encouraging proof of concept behind our approach to dendritic cell vaccines targeting telomerase, which is the backbone of the VAC2 program.

#### **Cell/Drug Delivery Technology - HyStem®**

HyStem is a patented biomaterial which mimics naturally occurring extracellular matrix, the structural network of molecules surrounding cells in organs and tissues essential to cellular function and tissue structure. Many tissue engineering and regenerative cell-based therapies will require the delivery of therapeutic cells in a matrix or scaffold for accurate anatomical placement, cell retention, and engraftment. HyStem is a unique hydrogel that has been shown to support cellular attachment and survival. 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, vascular and heart tissues.

The patented technology underlying our HyStem hydrogel products in development, such as Renevia, 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 200 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 have the ability to be formulated with cells and can be injected or applied as a gel, allowing it to conform to a cavity or space. This property offers several distinct advantages over other hydrogels, including the possibility of combining bioactive materials with the hydrogel at the point of use.

### Renevia<sup>®</sup>

*Renevia*, our lead facial aesthetics product candidate, is being developed as a potential treatment for facial lipoatrophy. Lipoatrophy is the loss of fat tissue and may be caused by several factors, including trauma, aging or drug side effects, such as those that can occur from certain drugs used to treat patients with human immunodeficiency virus (HIV). Renevia consists of our HyStem hydrogel combined with the patient's own fat or adipose progenitor cells. As a potential alternative to traditional fat transfer procedures, Renevia is designed to mimic the naturally-occurring extracellular matrix in the body and to provide a 3-D scaffold that supports effective cell transplant, retention, engraftment and metabolic support. Renevia is being developed with the goal of providing a natural looking and feeling, long-lasting option for facial volume restoration.

In 2017, Renevia met the primary endpoint of implanted volume retention in a pivotal clinical trial in Europe to assess its safety and effectiveness in restoring facial volume in patients whose subcutaneous fat, or adipose tissue, has been lost due to a side effect of certain drugs used to treat patients with HIV. In this clinical trial, Renevia treated patients retained approximately 100% of transplanted volume at six months ( $p < 0.001$ ), based on 3-D volume measurement of the implanted area, achieving the primary endpoint of the study. In addition to achieving the primary endpoint, treated patients retained an average 70% of the transplanted volume at 12 months and those patients that were observed after 18 months retained 64% of the transplanted volume. Based on these clinical trial results, in March 2018 we filed for marketing authorization in the European Union (EU) for certain forms of facial lipoatrophy. We anticipate feedback from the regulatory agency in the second half of 2019. If approved, we will seek to identify an external partner for commercialization of Renevia in Europe.

## Research Programs

### Vision restoration

In 2017, we expanded our ophthalmology portfolio by acquiring exclusive global rights to technology that allows the generation of three-dimensional human retinal tissue derived from human pluripotent 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 to potentially treat or prevent a variety of retinal degenerative diseases and injuries. In 2017, the National Institutes of Health (NIH) awarded us a grant of up to \$1.56 million to further develop this innovative, next generation vision restoration program for retinal diseases and injuries, which severely impact the quality of life for millions of people who have limited treatment options.

### Demyelination

OPC1 exhibits multiple reparative properties that have broad applicability to neurological injury and disease, particularly as a treatment for demyelination. Current research efforts are focused on the development of OPC1 as a candidate treatment for ischemic stroke and multiple sclerosis (“MS”), two severely debilitating conditions that: 1) afflict a large number of individuals (approximately 692,000 stroke cases and 10,000 new MS cases per year in the U.S. ([www.cdc.gov/stroke](http://www.cdc.gov/stroke), [www.nationalmssociety.org](http://www.nationalmssociety.org))), 2) lack any form of reparative treatment options, and 3) for which demyelination is a central component to their pathology.

To develop OPC1 as a treatment for MS, initial proof-of-concept efficacy data has been demonstrated in collaboration with Yale University using a non-human primate model of MS. Results of this study showed OPC1 engraftment that was associated with substantial remyelination of the lesioned primate spinal cord up to 5 months post-treatment. These data are in preparation for scientific publication. Subsequently, we initiated a collaboration with University of California Irvine to assess OPC1 efficacy in additional mouse models of MS that better recapitulate the autoimmune components of the disease. Preliminary results indicate that in addition to OPC1’s capacity to remyelinate the lesioned spinal cord, the cells may also help stimulate proliferation of a distinct class of immune cells known as regulatory T cells that can help reduce or eliminate autoimmunity. We intend to use the anticipated *in vivo* efficacy data obtained from the collaboration to seek additional non-dilutive funding for further development of OPC1 as a treatment for MS.

For ischemic stroke, initial proof-of-concept efficacy data for OPC1 has been demonstrated in a collaborative study with the University of California Los Angeles using a mouse model of white matter ischemic stroke. Results of this study demonstrated that within the stroke injury site, OPC1 cells engrafted, reduced lesion formation and inflammation, and increased myelination, culminating in improved functional recovery. We have since initiated a second preclinical study in collaboration with the University of South Florida to test two different doses of OPC1 in a

rat model of ischemic subcortical and white matter stroke. We expect this study to be completed in the second quarter of 2019. We intend to use the results of these combined studies to seek additional funding and guide further preclinical development of OPC1 as a treatment for ischemic stroke.

### Products for Orthopedic Indications

We also have research programs targeted at orthopedic indications. ReGlyde™ is another HyStem product in preclinical development as a device for viscosupplementation and as a platform for intraarticular drug delivery in osteoarthritis (OA). The viscosupplementation device program aims to administer ReGlyde directly into OA affected joints to provide joint lubrication to reduce pain and improve quality of life. The drug delivery program seeks to enable the sustained release of therapeutics in affected OA joints to help slow or reverse disease progression, in addition to alleviating pain and improving joint function.

These orthopedic programs are currently being conducted by OrthoCyte Corporation, an entity of which we own 99.8% of its outstanding capital stock.

**Subsidiaries and affiliates:**

The following table shows the companies in which we have a direct or indirect ownership, their respective principal fields of business, our percentage ownership as of March 11, 2019, and the country where their principal business is located:

<b>Company</b>	<b>Field of Business</b>	<b>BioTime Ownership</b>	<b>Country</b>
OncoCyte Corporation <sup>(1)</sup>	Cancer diagnostics	28%	USA
AgeX Therapeutics, Inc. <sup>(1)</sup>	PureStem <sup>®</sup> progenitor cell lines, brown adipose fat, induced tissue regeneration (“iTR”) technology	5%	USA
Cell Cure Neurosciences Ltd.	R&D and manufacturing of BioTime’s cell replacement platform technology	99% <sup>(2)</sup>	Israel
Asterias Biotherapeutics, Inc.	Cell based therapeutics to treat neurological conditions	100%	USA
ES Cell International Pte. Ltd <sup>(3)</sup>	Research and clinical grade cell lines	100%	Singapore
OrthoCyte Corporation <sup>(3)(4)</sup>	Research in orthopedic diseases and injuries	99.8%	USA

These are publicly traded companies. See Notes to Consolidated Financial Statements – Note 4. Deconsolidation and Distribution of AgeX and – Note 6. Equity Method of Accounting for Common Stock of OncoCyte, at Fair Value, included elsewhere in this Report for additional information. Beginning August 30, 2018, BioTime <sup>(1)</sup> deconsolidated AgeX and AgeX is no longer a subsidiary of BioTime as of that date but remains a marketable security for BioTime for the ownership interest retained. See “RECENT TRANSACTIONS AFFECTING OUR CORPORATE ORGANIZATION,” above.

Includes shares owned by BioTime and ES Cell International Pte. Ltd. During June and July of 2017, we increased our ownership of Cell Cure by acquiring all of the Cell Cure ordinary shares and Cell Cure convertible promissory notes held by its second largest shareholder, Hadasit Bio-Holdings Ltd., and all of the Cell Cure ordinary shares held by its third largest shareholder, Teva Pharmaceutical Industries, Ltd. As a result of this acquisition, we now <sup>(2)</sup> own, directly and through a wholly-owned subsidiary, approximately 99% of the outstanding Cell Cure ordinary shares. In July 2018, we terminated the Cell Cure stock option plan and all Cell Cure issued and outstanding stock options were canceled in exchange for 775,000 BioTime stock options issued to the Cell Cure employees (see Notes to Consolidated Financial Statements - Note 13. Stock Based Awards, included elsewhere in this Report for additional information).

<sup>(3)</sup> The operating activities and fields of business listed under these subsidiaries are conducted primarily by BioTime as the parent company.

<sup>(4)</sup> OrthoCyte 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 employees, including officers. As of

December 31, 2018, options to purchase 1,249,000 shares of OrthoCyte common stock had been granted.

## **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 February 28, 2019, we owned or controlled or licensed directly or through our subsidiaries approximately 850 patents and pending patent applications worldwide including more than 190 issued or pending U.S. patents or patent applications. This number also includes the over 135 patents and applications licensed from WARF.

### **OpRegen**

We and our subsidiary, Cell Cure, have issued patents that will provide protection to OpRegen. The issued patents have expiry dates ranging from 2025 to 2033. We and our subsidiary, Cell Cure also have pending applications that if issued, will provide protection to OpRegen and will have expiry dates ranging from December 2025 to December 2038.

Cell Cure was a party to two pending opposition proceedings in the European Patent Office (EPO) 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 took place on March 16, 2017 and March 17, 2017, respectively. Both patents were upheld by the EPO. The decisions were both appealed and the detailed grounds for appeal were due on September 9, 2017 and September 11, 2017, respectively, however, both appeals were withdrawn prior to those dates and the patents will be issued as amended in the opposition proceedings. Both patents relate to our OpRegen product and provide protection until April 2028. There are additional patent applications pending that if issued will provide further protection for OpRegen.



## **Renevia**

We have patent protection for Renevia with expiry dates ranging from May 2023 to August 2027, and pending applications that if issued, will provide protection to Renevia with expiry dates ranging from December 2024 to June 2038.

## **OPC1**

The patent rights relevant to neural cells, such as oligodendrocyte progenitor cells, include various patent families acquired from Geron that are directed to the differentiation of pluripotent stem cells (including hES cells) into various neural cell types, as well as various culture and purification methods. These patent rights also include rights licensed from the Regents of the University of California. There are issued patents in the United States, Australia, Canada, Europe, Japan, China, Hong Kong, India, Korea, Singapore and Israel. Additionally, there are five new pending patent families owned by us directed to improved methods of producing oligodendrocyte progenitor cells, oligodendrocyte progenitor cell compositions and methods of treatment of spinal cord injury and stroke using oligodendrocyte progenitor cells. The stroke family is jointly owned with the Regents of the University of California the other four new pending families are solely owned by Asterias. The expiration dates of the patents acquired from Geron and in-licensed from the Regents of the University of California will be within 2021 to 2030. The potential expiry dates of the four new patent families with applications pending will be within 2036 to 2038. The commercial success of OPC1 product depends, in part, upon our ability to exclude competition for this product with the existing patent portfolio, regulatory exclusivity, or a combination of both.

## **VAC1 and VAC2**

The patent rights relevant to dendritic cells include various patent families acquired from Geron or in-licensed from third parties that are directed to the differentiation of pluripotent stem cells (including hES cells) into hematopoietic progenitor cells and immature and mature dendritic cells. In addition, these patent rights include a patent family with claims directed to immunogenic compositions comprising antigen-presenting dendritic cells and methods of eliciting an anti-telomerase immune response in a subject by administering to the subject such compositions. There are issued patents in the United States, Australia, Europe, Canada, China, Hong Kong, Japan, Korea, Israel and Singapore. The expiration dates of the patents acquired from Geron and in-licensed to us range from 2019 to 2029. Additionally, there is a new pending patent family owned by us with claims directed to immunotherapeutic compositions comprising immunogenic peptides and methods of eliciting a cellular mediated immune response in a subject, with a provisional patent application filed in 2017. The potential expiry date of the new patent family with a pending provisional application will be in 2038. The commercial success of VAC1 and VAC2 products depends, in part, upon our ability to exclude competition in these products with this patent portfolio, regulatory exclusivity, or a combination of both.

In addition, we have issued patents in the United States and various other jurisdictions for producing cardiomyocytes, pancreatic islet cells, hepatocytes, chondrocytes, and osteoblasts. The expiration dates of these patents range from 2020 to 2032.

### **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 any amounts that we may accrue on our financial statements as a reserve for contingent liabilities. 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.

## **EMPLOYEES**

As of December 31, 2018, we had 79 employees, of which 36 are BioTime employees and 43 are employees of our subsidiaries, including foreign subsidiaries, and of which 76 are employed on a full-time basis and three are employed on a part-time basis. 17 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. In connection with our updated corporate objectives with a greater focus on clinical development, we reduced our worldwide headcount by 16 employees through employee terminations and the closing of vacant positions since December 31, 2017.

## **MANUFACTURING**

### **Cell Products**

We established an innovative cell therapy manufacturing facility in the Bio Park on the campus of the Hadassah University Hospital in Jerusalem, Israel. The facility includes process development laboratories and a state-of-the-art, cGMP manufacturing facility. It is designed and equipped to enable simultaneous GMP processes and to produce OpRegen and a range of cell therapy products for human use in clinical trials as well as at a scale suitable for commercial launch. We intend to transfer all cGMP manufacturing processes, including the establishment of H1 cell banks and the OPC1 process development and manufacturing for clinical studies, to this facility.

### **HyStem Hydrogel Products**

We hold a California Device Manufacturing License and are registered with the FDA as a Device Manufacturer in support of our 510K cleared product, Premvia. We have ISO 13485:2003 certification for the design, development, manufacture, and distribution of hydrogels for therapeutic delivery applications. Although we hold these certifications, licenses, and registrations, all our HyStem® Hydrogel product manufacturing occurs at contract facilities located in Pennsylvania and California. Our contractors have the necessary registrations and certifications to

perform this manufacturing.

### **Plasma Volume Expanders**

BioTime has licensed Hextend rights to Hospira, Inc., a subsidiary of Pfizer, Inc., for the United States and to CJ Healthcare for South Korea. CJ Healthcare manufactures, markets and distributes our synthetic blood volume expander solution Hextend for use in the respective geographies. We receive royalties on the sales of Hextend.

### **RAW MATERIALS**

Except as described below, we believe the raw materials and supplies that we require to manufacture our products, as well as the raw materials that we require for our research and development operations relating to our product candidates and products, are widely available from numerous suppliers and are generally considered to be generic materials and supplies. Except as described below, we do not rely on a single supplier for the current production of any product in development or for our research and development operations relating to our products.

We usually contract with suppliers to purchase the materials required for the research and development operations of our products. All the materials required in the research and development operations of our products are off-the-shelf pharmaceutical products; special production or special requirements are not required to order these materials. We have no written agreements with most of our suppliers. Rather, we submit purchase orders to our suppliers from time to time and as required.

Most of the ingredients in the HyStem products we are developing are readily obtainable from multiple sources. Two critical ingredients, gelatin and sodium hyaluronate, are readily available from multiple sources but would require significant testing in order to qualify new vendors as sources of those ingredients for our products.

### **LICENSED TECHNOLOGY AND PRODUCT DEVELOPMENT AGREEMENTS**

BioTime has 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.

### **HyStem Hydrogel Technology**

In February 2006, we 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 health 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 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.

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.

### **Hadasit Research and License Agreement**

In June 2017, Cell Cure entered into a Second Amended and Restated License Agreement (the “Hadasit License Agreement”) with Hadasit Medical Research Services and Development Ltd. (“Hadasit”), the commercial arm and a wholly-owned subsidiary of Hadassah Medical Organization. Pursuant to the Hadasit License Agreement, Hadasit granted Cell Cure an exclusive, worldwide, royalty bearing license (with the right to grant sublicenses) in its intellectual property portfolio of materials and technology related to human stem cell derived photoreceptor cells and

retinal pigment epithelial cells (the “Licensed IP”), to use, commercialize and exploit any part thereof, in any manner whatsoever in the fields of the development and exploitation of (i) human stem cell derived photoreceptor cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders, and (ii) human stem cell derived retinal pigment epithelial cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders.

As consideration for the Licensed IP, Cell Cure paid a small one-time lump sum payment for reimbursement of intellectual property related expenses and will pay a royalty in the mid-single digits of net sales from sales of Licensed IP by any invoicing entity, and a royalty of 21.5% on sublicensing receipts. In addition, Cell Cure will pay Hadasit an annual minimal non-refundable royalty, which will become due and payable the first January 1 following the completion of services to Cell Cure by a research laboratory.

Cell Cure agreed to pay Hadasit non-refundable milestone payments upon the recruitment of the first patient for the first Phase IIB clinical trial, upon the enrollment of the first patient in the first Phase III clinical trials, upon delivery of the report for the first Phase III clinical trials, upon the receipt of an NDA or marketing approval in the European Union, whichever is the first to occur, and upon the first commercial sale in the United States or European Union, whichever is the first to occur. Such milestones, in the aggregate, may be up to \$3.5 million. As of December 31, 2018, Cell Cure had not accrued any of these milestone payments.

The Hadasit License Agreement terminates upon the expiration of Cell Cure’s obligation to pay royalties for all licensed products, unless earlier terminated. In addition, the Hadasit License Agreement may be terminated by (i) Hadasit if, among other reasons, Cell Cure fails to continue the clinical development of the Licensed IP or fails to take actions to commercialize or sell the Licensed IP over any consecutive 12 month period, and (ii) by either party for (a) a material breach which remains uncured following a cure period, or (b) the granting of a winding-up order in respect of the other party, or upon an order being granted against the other party for the appointment of a receiver or a liquidator in respect of a substantial portion of such other party’s assets. The Hadasit License Agreement also contains customary indemnification obligations of Cell Cure.

## **License Agreement with University of California**

Geron assigned to Asterias its exclusive license agreement with The Regents of the University of California dated June 2018 (the “UC License Agreement”) for patents covering a method for directing the differentiation of pPS cells to glial-restricted progenitor cells that generate pure populations of oligodendrocytes for remyelination and treatment of spinal cord injury. Under the UC License Agreement, we have an exclusive worldwide license under such patents, including the right to grant sublicenses, to create products for biological research, drug screening, and human therapy using the licensed patents.

Under the UC License Agreement, we will pay the university a royalty of 1% from sales of products that are covered by the licensed patent rights, and a minimum annual royalty of \$5,000 starting in the year in which the first sale of a product covered by any licensed patent rights occurs and continuing for the life of the applicable patent right under the agreement. Under certain conditions, we will pay the university 7.5% of any proceeds, excluding debt financing and equity investments, and certain reimbursements, that we receive from sublicensees.

The UC License Agreement terminates on the expiration of the last-to-expire of the university’s issued licensed patents. If no further patents covered by the UC License Agreement are issued, it will terminate in 2024. The university may terminate the UC License Agreement if we breach it, and we can terminate it upon 60 days’ notice.

## **World-Wide Non-Exclusive WARF License**

In October 2013, Asterias entered into a Non-Exclusive License Agreement with the Wisconsin Alumni Research Foundation (“WARF”) under which Asterias was granted a worldwide non-exclusive license under certain WARF patents and WARF-owned embryonic stem cell lines to develop and commercialize therapeutic, diagnostic and research products. The licensed patents include patents covering methods for growth and differentiation of primate embryonic stem cells. The licensed stem cell lines include the H1, H7, H9, H13, and H14 hES cell lines.

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

The license agreement will terminate with respect to licensed patents upon the expiration of the last licensed patent to expire; with respect to the licensed stem cell lines, the license agreement will remain in force until terminated by

either party in accordance with the termination provisions. We may terminate the license agreement at any time by giving WARF prior written notice. WARF may terminate the license agreement if: (1) payments of earned royalties, once begun, cease for a specified period of time, (2) we and any third parties collaborating or cooperating with us in the development of products using the licensed patents or stem cell lines fail to spend a specified minimum amount on research and development of products relating to the licensed patents or stem cell lines for a specified period of time, or (3) we breach the license agreement or become bankrupt or insolvent or if any of the licensed patents or stem cell lines are offered to creditors.

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

### **Royalty Agreement with Geron**

In connection with Asterias's acquisition of Geron's stem cell assets, in October 2013, we entered into a royalty agreement with Geron (the "Royalty Agreement") pursuant to which we agreed to pay Geron a 4% royalty on net sales (as defined in the Royalty Agreement) by us or any of our affiliates or sales agents of any products that we develop and commercialize that are covered by the patents Geron contributed to us. In the case of sales of such products by a person other than us or one of our affiliates or sales agents, we will be required to pay Geron 50% of all royalties and cash payments received by us or by our affiliate in respect of a product sale. Royalty payments will be subject to proration in the event that a product covered by a patent acquired from Geron is sold in combination with another product that is not covered by a patent acquired from Geron. The Royalty Agreement will terminate at the expiration or termination date of the last issued patent contributed by Geron under the Royalty Agreement. We estimate that the latest patent expiration date will be in 2032.

### **AgeX License Agreement**

Concurrently with our contribution of assets to AgeX in August 2017, we and AgeX entered into a license agreement pursuant to which we licensed to AgeX, with rights to sublicense, certain intellectual property, including patents and patent applications and know-how for use in the development, manufacture and commercialization of products or services for the prevention, treatment, amelioration, diagnosis or monitoring of all human and non-human animal diseases and conditions except for the field of medical products, devices and services for the reserved BioTime fields of orthopedic, ophthalmic and medical aesthetic uses. In addition, we retained an option right to license, on terms to be negotiated, certain patents in research, development, manufacturing and commercialization of treatments in the reserved BioTime fields. The licensed patents and know-how relate generally to (a) our PureStem human embryonic progenitor cell lines, and (b) telomere length and DNA quality control analysis in pluripotent stem cells.



The BioTime patent rights licensed to AgeX are exclusive and worldwide except for existing third-party licenses, and for medical products, devices, and services related to tendon. AgeX also received an option to license certain BioTime retained patent rights outside of orthopedic indications unless a license grant would compete with a BioTime program or products in the retained BioTime field.

We also agreed to license or sublicense to AgeX certain additional patents and patent rights and know-how relating to BioTime HyStem hydrogel technology, human embryonic progenitor cell technology, and human pluripotent stem cell lines and technology for use outside the fields reserved to BioTime or in the case of certain sublicense rights in fields previously licensed to third parties.

## **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, safety, efficacy, distribution, labeling, packaging, storage, record keeping, marketing, import/export and promotion of drugs, biologics, and medical devices. Laboratories performing diagnostic tests such as those being developed by OncoCyte are also subject to regulation at both the federal and state level. Authorities also heavily regulate many of these activities for human cells, tissues, and cellular and tissue-based products or HCT/Ps.

### **FDA and Foreign Regulation of Therapeutic Products**

The FDA and foreign regulatory authorities will regulate our proposed products as drugs, biologics, 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 biologics 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 HCT/Ps are subject to additional registration and listing requirements, including current good tissue practice regulations. Certain cell therapy 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 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.

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.

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 not a 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 drug is eligible for designation as a regenerative medicine advanced therapy (“RMAT,” formerly known as “Regenerative Advanced Therapy”) 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 RMAT designation. RMAT designation allows for similar benefits as the breakthrough therapy designation. There is no assurance that the FDA will grant RMAT 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.

### **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 countries in which we may seek approval of our product candidates.

### **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 and 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 previously 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 the new Executive Order and existing law. In accordance with this Executive Order and existing law, the NIH adopted guidelines that went into effect July 7, 2009. The central focus of the guidelines was 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, were and remain ineligible for use in federally funded research.

In addition to President Obama's Executive Order, bipartisan legislation was introduced on June 19, 2013 in the U.S. House of Representatives which would allow for Federal funding of hES research. The House bill is similar to one that was previously approved by both Houses of Congress but vetoed by President Bush. The House bill provides that hES cells would 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 were created using in vitro fertilization for reproductive purposes, and are no longer needed by the individuals seeking such treatment, and (2) the individuals seeking reproductive treatment donated the embryos to be used for research purposes with written and voluntary informed consent and without receiving any financial or other inducements to make the donation. The House bill would authorize the Department of Health and Human Services ("HHS") and the NIH to adopt further guidelines applicable to the conduct or support of human stem cell research consistent with this proposed legislation.

Although no legislation permitting Federal funding of hES research has been advanced by Congress, the scope of the Dickey-Wicker Amendment, which prohibits the use of federal funding for activity related to the harm or destruction of a human embryo, was determined by the U.S. Court of Appeals for the D.C. Circuit not to preclude funding of hES research. With the Supreme Court declining review of the appeal in 2013, the ruling has been allowed to stand. Additionally, the 21st Century Cures Act, signed into law in 2016, included provisions facilitating timely FDA review and approval of regenerative cell therapies enabled by stem cell therapy research, albeit limited to adult stem cells.

## **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, including research involving the creation or use of human embryos, obtain approval in

writing from a Stem Cell Research Oversight Committee (“SCRO Committee”) before conducting the research. Under certain California regulations, all hES cell lines that will be used in our research must be acceptably derived.

We also comply with certain California regulations that require certain records to be maintained with respect to stem cell research and the materials used.

We have formed a SCRO Committee which reviews each of BioTime’s projects that involve the use of pluripotent stem cells. The Committee reviews and confirms that we are using only hES cell lines that have been acceptably derived and that the research conducted using these cell lines is both scientifically and ethically justified under existing California regulations. The OpRegen program has been reviewed by the SCRO Committee and we believe that we comply with applicable federal and state guidelines. The hES cell lines that we use are all on the NIH registry of lines that have been reviewed and meet standards for federal funding grants.

### **Health Insurance Portability and Accountability Act**

Under the Health Insurance Portability and Accountability Act (“HIPAA”), the HHS has issued regulations to protect the privacy and security of protected health information. 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.

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, to induce or in return for either the referral of an individual, or the furnishing, recommending, or arranging for the purchase, lease or order of any health care item or service reimbursable, in whole or in part, under a federal health care program. The definition of “remuneration” has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, ownership interests and providing anything at less than its fair market value. Recognizing that the federal 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. Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, ACA) codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

The federal civil and criminal false claims laws, including the federal False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent.

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. 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.

The federal Physician Payments Sunshine Act which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

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, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or that apply regardless of payor, state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing

expenditures, state laws that require the reporting of information related to drug pricing, and state and local laws requiring the registration of pharmaceutical sales and medical representatives.

Additionally, the U.S. Foreign Corrupt Practices Act (“FCPA”) prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

If our operations are found to be in violation of any of the laws described above, or any other governmental regulations that apply to us, we may be subject significant civil, criminal and administrative sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.



## Coverage and Reimbursement

Patients generally rely on third-party payors to reimburse part or all of the costs associated with medical products. Accordingly, market acceptance of medical products can depend on the extent to which third-party coverage and reimbursement is available from government health administration authorities, private healthcare insurers and other healthcare funding organizations.

For example, 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. Pharmaceutical companies may be required to provide specified rebates or discounts on the products it sells to certain government funded programs, including Medicare and Medicaid, and those rebates or discounts have increased over time. The ACA increased many of these mandatory discounts and rebates required and imposed a new Branded Prescription Pharmaceutical Manufacturers and Importers fee payable each year certain pharmaceutical companies and manufacturers.

Outside of the United States, 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. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

## 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, 2018 and 2017:

Sources of Revenues	Year Ended December 31,	
	2018	2017
NIH grant income <sup>(1)</sup>	21.2%	5.0%

## Edgar Filing: BIOTIME INC - Form 10-K

IIA (formerly OCS) grant income (Cell Cure, Israel)	50.4%	43.2%
Subscriptions, advertising, licensing and other (various customers) <sup>(2)</sup>	20.5%	49.4%
Sale of research products	4.2%	-%
Other	3.7%	2.4%

(1) For 2018, reflects income from grants to BioTime from the National Institutes of Health (NIH).

(2) For 2018 and 2017, one individual customer represents greater than 5% of total revenues. These revenues were generated by LifeMap Sciences, which is a subsidiary of AgeX. The 2018 revenues shown are for the period January 1, 2018 through August 29, 2018. As a result of the AgeX Deconsolidation on August 30, 2018, BioTime does not expect to recognize subscription and advertisement revenues during subsequent accounting periods

### Geographic Area

	Year Ended December 31,	
	2018	<b>2017</b> (1)
United States	\$1,804	\$1,651
Foreign <sup>(2)</sup>	3,184	1,807
Total revenues	\$4,988	\$3,458

(1) Amounts recognized prior to adoption of Topic 606 have not been adjusted under the Topic 606 modified retrospective transition method.

(2) Foreign revenues are primarily generated from grants in Israel.

### MARKETING

#### Plasma Volume Expanders

Hextend<sup>®</sup> is being distributed in the U.S. by Hospira and in South Korea by CJ Healthcare under exclusive licenses from us. 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 Healthcare 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.

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

We believe that some of our competitors are trying to develop 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. Ocata, which was recently acquired by a subsidiary of Astellas Pharma Inc., and Retinal Patch Technologies Inc. are conducting clinical trials of a hES cell products designed to treat age-related macular degeneration. If their products are proven to be safe and effective, they may reach the market ahead of 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 U.S. 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.

## **ITEM 1A. RISK FACTORS**

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

### **Risks Related to Our Business Operations and Capital Requirements**

**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, 2018 and 2017 were \$41.8 million and \$38.9 million respectively, and we had an accumulated deficit of \$262 million, as of December 31, 2018. Generally, we have primarily financed our operations through sales of our equity securities, licensing fees, royalties on product sales by our licensees, research grants, and subscription fees and advertising revenue from database products. In August 2018, we sold 14,400,000 of our shares of AgeX common stock to Juvenescence Limited for aggregate gross proceeds of approximately \$43 million, which we will also use to finance our operations. From and after that transaction, we will no longer recognize revenues from subscription fees and advertising revenue from the sale database products of LifeMap Sciences, an AgeX subsidiary. To partially cover our operating costs, we also charge fees for shared services we perform and office and laboratory space we provide to both OncoCyte and AgeX, which can be terminated by either party. Ultimately, our ability to generate sufficient operating revenue to earn a profit depends upon our success in developing and marketing or licensing products and technology.

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

We are attempting to develop new medical products and technology. None of our experimental products and technologies has received regulatory approval for commercialization. These new products and technologies might not prove to be safe and efficacious in the human medical applications for which they are being developed. Our research and development activities are costly, time consuming, and their results are uncertain. We incurred research and development expenses amounting to \$21.0 million and \$24.0 million during the fiscal years ended December 31, 2018 and 2017, respectively. If successfully develop 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 large sums of money. Clinical trials of new therapeutic products, particularly those products that are regulated as biologics, drugs, or devices, are very expensive and take years to complete. We may not have the financial

resources to fund clinical trials on our own and we may have to enter into licensing or collaborative arrangements with others. Any such arrangements may be dilutive to our ownership or economic interest in the products we develop, and we might have to accept royalty payments on product sales rather than receiving the gross revenues from product sales. In addition, we may discontinue one or more of the research or product development programs. Our product and technology development programs may be delayed or discontinued should adequate funding on acceptable terms not be available.

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

At December 31, 2018, we had \$30.7 million of cash, cash equivalents and marketable equity securities on hand, including the \$21.6 million of proceeds we received through the sale of a significant portion of our AgeX shares to Juvenescence in August 2018, there can be no assurance that we or our subsidiaries will be able to raise additional funds on favorable terms or at all, or that any funds raised will be sufficient to permit us or our subsidiaries to develop and market our products and technology. Unless we are able to generate sufficient revenue or raise additional funds when needed, it is likely that we will be unable to continue our planned activities, even if we make progress in our research and development projects. We may have to postpone or limit the pace of our research and development work and planned clinical trials of our product candidates unless our cash resources increase through a growth in revenues or additional equity investment or borrowing.

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

We expect to continue to incur substantial research and product development expenses and will need to raise additional capital to pay operating expenses until we are able to generate sufficient revenues from product sales, royalties and license fees. Our ability 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. Any equity capital raise could result in the dilution of the interests of shareholders or may otherwise limit our ability to finance further in the future, which may negatively impact our business and operations. Any debt capital financing may involve covenants that restrict our operations, including limitations on additional borrowing and on the use of our assets. If we raise capital through licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to us. There can be no assurance that we will be able to raise capital on favorable terms, or at all, or at times and in amounts needed to successfully finance product development, clinical trials, and general operations.

**Failure to successfully combine the businesses of BioTime and Asterias in the expected time frame or realize the expected benefits of such combination may adversely affect our future results.**

The success of our acquisition of Asterias will depend, in part, on our ability to realize the anticipated benefits from combining its business with ours. To realize these anticipated benefits, the businesses of BioTime and Asterias must be successfully combined. Our management may face significant challenges in consolidating the functions of BioTime and Asterias, integrating the technologies, organizations, procedures, policies and operations, as well as integrating the different business cultures of the two companies, prioritizing the scientific and clinical programs and retaining key personnel. If we are unable to successfully integrate Asterias' operations, the anticipated benefits of the acquisition may not be realized fully or at all, may require significant investment to achieve the benefits or may take longer to realize than expected. The integration process and other disruptions resulting from the acquisition may also disrupt each company's ongoing businesses and/or adversely affect our relationships with employees, regulators and others with whom we have business or other dealings.

**Integrating the companies may divert our resources and management's attention away from our operations.**

Successful integration of Asterias' operations, products and personnel with ours following the acquisition may be complex, time consuming and place a significant burden on our management and internal resources. The diversion of management attention and any difficulties encountered in the transition and integration process could harm our business, financial condition, operating results and evaluating strategic actions.

**A lawsuit has been filed and other lawsuits may be filed against Asterias, BioTime and certain members of their respective boards of directors challenging the Asterias merger. An adverse ruling in any such lawsuit may result in additional payments and costs.**

On February 19, 2019, a putative class action lawsuit relating to the Asterias acquisition was filed on behalf of Asterias shareholders in the Superior Court of the State of California in the County of Alameda against, among other parties, Asterias, the members of Asterias' board of directors, BioTime, Neal Bradsher, Broadwood Capital, Inc. and Broadwood Capital Partners, L.P. The lawsuit asserts claims for breach of fiduciary duty and aiding and abetting breach of fiduciary duty, alleging that the consideration Asterias shareholders are to receive in the merger is unfair, the merger is the product of an unfair process, and the joint proxy statement omits certain allegedly material information. The complaint seeks, injunctive relief or rescissory damages and an award of plaintiffs' expenses and attorneys' fees.

The defendants specifically deny all allegations in the litigation, including that any additional disclosure was or is required and intend to defend it vigorously. To moot the disclosure claims in the complaint, Asterias and BioTime made supplemental disclosures to the joint proxy statement relating to the merger. However, any adverse ruling in



these cases could result in additional payments. Additional lawsuits arising out of or relating to the merger agreement and/or the merger may be filed in the future.

**Comprehensive tax reform legislation could adversely affect our business and financial condition.**

The U.S. government has enacted comprehensive tax legislation, known as the Tax Cuts and Jobs Act of 2017 (“Tax Act”) that includes significant changes to the taxation of business entities. This federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income for net operating losses generated after December 31, 2017 and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the federal tax law.

**Our ability to use net operating losses to offset future taxable income may be subject to limitations.**

As of December 31, 2018, we had federal and state gross net operating loss (“NOLs”) carryforwards of approximately \$136.9 million. The federal and state NOL carryforwards will begin to expire, if not utilized, in varying amounts between 2028 and 2037. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under federal income tax law, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the “IRC”, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Under the provisions of the IRC, changes in our ownership, in certain circumstances, will limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, IRC Section 382 imposes limitations on a company’s ability to use NOLs upon certain changes in such ownership. Calculations pursuant to IRC Section 382 can be very complicated and no assurance can be given that upon further analysis, our ability to take advantage of our NOLs may be limited to a greater extent than we currently anticipate. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to utilize our NOLs fully. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership that we cannot predict or control that could result in further limitations being placed on our ability to utilize our federal NOLs.

**Failure in our information technology and storage systems could significantly disrupt the operation of our business.**

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology (“IT”) systems. IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our and our vendors’ servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite precautionary measures to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

**Our business and operations could suffer in the event of 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 including earthquakes and tsunamis, terrorism, war, and telecommunication and electrical failures. Such events could cause significant interruption of our operations and development programs. 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.

In addition, our product candidates are manufactured by starting with cells that are stored in a cryopreserved master cell bank. While we believe we have adequate backup should any cell bank be lost in a catastrophic event, it is possible that we or our third-party suppliers and manufacturers could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks. See “—We will face risks related to our own manufacturing capabilities and those related to our reliance on third parties to manufacture product.” We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates or products. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products and could have an adverse effect on our business, prospects, financial condition and results of operations.

**Significant disruptions of information technology systems or data security breaches could adversely affect our business.**

We are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such information. We have also outsourced some of our operations (including parts of our information technology infrastructure) to a number of third-party vendors who may have, or could gain, access to our confidential information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties.

Our information technology systems are large and complex and store large amounts of confidential information. The size and complexity of these systems make them potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third party vendors and/or business partners, or from cyber-attacks by malicious third parties. Attacks of this nature are increasing in frequency, persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of important information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of our information. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue.

Significant disruptions of our, our third party vendors’ and/or business partners’ information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. Any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. In addition, security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may further harm us. Moreover, the prevalent use of mobile devices to access confidential information increases the risk of security breaches. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business. In addition, failure to maintain effective internal accounting controls related to security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny.

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

We believe that our continued success depends to a significant extent upon our efforts and ability to retain highly qualified personnel, including our Chief Executive Officer, Brian Culley. All of our officers and other employees are at-will employees and may terminate their employment with us at any time with no advance notice. The loss of the services of Mr. Culley or other members of our senior management could have a material adverse effect on us. Further, the replacement of any of such individuals likely would involve significant time and costs and may significantly delay or prevent the achievement of our business and clinical objectives and would harm our business.

**The value of our investments in other companies fluctuates based on their respective stock prices and could be negatively impacted by poor business performance.**

We have equity investments in several publicly-listed companies, including OncoCyte and AgeX. As of March 13, 2019, the value of our investments in OncoCyte and AgeX was \$63.1 million based on their stock prices as of that date. If these companies were to have delays in clinical trials or commercialization activities, the value of their common stock and the valuation of our investment could be negatively impacted. If these companies were to fail and ultimately cease operations, we may lose the entire value of our investments.

**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.

## Risks Related to Government Regulation

**We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, it could face substantial penalties.**

If we obtain FDA approval for any of our product candidates or technologies and begin commercializing those products or technologies in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws, including the federal False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, (“HITECH”) and their implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;

The Physician Payments Sunshine Act which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payors, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, state and local laws that require the registration of pharmaceutical sales and medical

representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government health care programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

**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.

**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 guidelines for determining the eligibility of hES cell lines for use in federally funded research. The central focus of the 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.

**We expect that the commercial opportunity for some of our products may depend on our ability to obtain reimbursement and continued coverage from various payors, including government entities and insurance companies.**

If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products 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.

For example, 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, as amended by the Health Care and Education Reconciliation Act (collectively, 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.

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.

**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. Among the ACA's provisions of importance to our industry are that it:

- created the Branded Prescription Pharmaceutical Manufacturers and Importers annual fee;
- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- created new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded the entities eligible for discounts under the Public Health program;
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established a Centers for Medicare & Medicaid Innovation at [the Centers for Medicare & Medicaid Services] CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011; and
- created a licensure framework for follow on biologic products.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing

penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, and delaying the implementation of certain ACA-mandated fees. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. On January 31, 2019, the [U.S. Department of Health and Human Services, Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

**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 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 will 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 may 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 are facing heightened scrutiny of their relationships with health care providers from anti-corruption enforcement officials. In addition, health care companies 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 bring products to the market globally.

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

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.

**Even if we receive approval for our products, we may be subject to extensive regulatory obligations in order to commercialize our products.**

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 outweighs 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. Any of these requirements or actions may negatively impact our business or operations.

**If we are deemed to be an investment company, we may have to institute burdensome compliance requirements and our activities may be restricted.**

An entity that, among other things, is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, owning, trading or holding certain types of securities would be deemed an investment company under the Investment Company Act of 1940, as amended (the “1940 Act”). Based on the securities we hold, including our equity ownership in publicly traded companies, we may not meet the requirements for an exemption promulgated under the 1940 Act. If we are deemed to be an investment company under the 1940 Act, we would be subject to additional limitations on operating our business, including limitations on the issuance of securities, which may make it difficult for us to raise capital.

## **Risks Related to Our Clinical Development and Commercial Operations**

**Clinical studies are costly, time consuming and are subject to risks that could delay or prevent commercialization of our current or future product candidates.**

We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

inability to generate satisfactory preclinical, toxicology, or other *in vivo* or *in vitro* data or diagnostics to support the initiation or continuation of clinical studies necessary for product approval;

delays in securing clinical investigators and agreeing on acceptable terms with contract research organizations (“CROs”) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and clinical study sites;

delays in obtaining required Institutional Review Board (“IRB”) approval at each clinical study site;

failure to obtain permission from regulatory authorities to conduct a clinical study after review of an investigational new drug (“IND”) or equivalent foreign application or amendment;

slower than anticipated rates of patient recruitment and enrollment, failing to reach the targeted number of patients due to competition for patients from other trials, or patients dropping out of our clinical studies once enrolled;

failure by clinical sites or our CROs or other third parties to adhere to clinical study requirements or report complete findings;

failure to perform the clinical studies in accordance with the FDA’s good clinical practices requirements or applicable foreign regulatory guidelines;

occurrence of adverse events associated with our product candidates or with product candidates of third parties that may have characteristics similar to or perceived to be similar to our product candidates;

negative or inconclusive results from our clinical trials which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or to curtail or abandon development programs for a product candidate;

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

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;

unavailability of clinical trial supplies;

inability to use clinical trial results from foreign jurisdictions to support U.S. regulatory approval;

changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

the cost of clinical studies of our product candidates; and

delays in agreeing on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical studies.

Any inability to successfully complete clinical development and obtain regulatory approval could result in additional costs to us or impair our ability to generate revenue. Clinical study delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do and may harm our business and results of operations.

**Preliminary data and interim results we disclose, and results from earlier studies, may not be predictive of the final results, or of later studies or future clinical trials.**

All of our product candidates are still in an early stage of development, and no assurances can be given that the development of any of our product candidates will ultimately be successful. Although we may from time to time disclose results from preclinical testing or preliminary data or interim results from our clinical studies of our product candidates, and earlier clinical studies, including clinical studies with similar product candidates, are not necessarily predictive of future results, including clinical trial results.

The results of our current and future clinical trials may differ from results achieved in earlier preclinical and clinical studies for a variety of reasons, including:

we may not demonstrate the potency and efficacy benefits observed in previous studies;

our efforts to improve, standardize and automate the manufacture of our product candidates, including OpRegen, OPC1 and VAC2, and any resulting deviations in the manufacture of our product candidates, may adversely affect the safety, purity, potency or efficacy of such product candidates;



differences in study design, including differences in size, eligibility criteria, and patient populations;

advancements in the standard of care may affect our ability to demonstrate efficacy or achieve study endpoints in our current or future clinical trials;

safety issues or adverse events in patients that enroll in our current or future clinical trials; and

results in preclinical and clinical tests may not be repeated in subsequent tests or be predictive of future results.

Even if our current and planned clinical trials are successful, we will need to conduct additional clinical trials, which may include registrational trials, trials in additional patient populations or under different treatment conditions, and trials using different manufacturing protocols, processes, materials or facilities or under different manufacturing conditions, before we are able to seek approvals for our product candidates from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Our failure to meet the requirements to support marketing approval for our product candidates in our ongoing and future clinical trials would substantially harm our business and prospects.

**The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors, other health care providers and others in the medical community.**

Even if a product candidate obtains regulatory approval, its commercial success will depend in part on physicians, patients, third-party payors, other health care providers and others in the medical community accepting our product candidates as medically useful, cost-effective, and safe. Any product we bring to the market may not gain market acceptance by such parties. The degree of market acceptance of any of our products will depend on several factors, including without limitation:

the efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;

the prevalence and severity of the disease and any side effects;

the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;

the convenience and ease of administration;

the cost of treatment, particular as additive to existing treatments;

the willingness of the patients and physicians to accept and use these therapies;

the marketing, sales and distribution support for the products;

the publicity concerning our products or competing products and treatments; and

the pricing and availability of third-party insurance coverage and reimbursement.

Even if a product displays a favorable efficacy and safety profile upon approval, market acceptance of the product will be uncertain. Efforts to educate the medical community and third-party payors on the benefits of the products may require significant investment and resources and may never succeed. If our products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, other health care providers and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

**If the market opportunities for our product candidates are smaller than we believe and estimate they are, we may not meet our revenue expectations and, even assuming approval of a product candidate, our business may suffer.**

Our projections of the number of potential users in the markets we are attempting to address are based on our beliefs and estimates. Bear in mind:

Our estimates have been derived from a variety of sources, including market research and publications and scientific literature estimating the total number of potential patients and currently approved or used therapies. Our estimates are also based on assumptions regarding the potential size of the market assuming broad regulatory approval or potential usage by physicians beyond the approved label. Any of our estimates may prove to be incorrect.

The scope of approval and potential use of any product candidate may be significantly narrower, and the number of patients may turn out to be lower than expected.

Competitive products or approaches may be approved or come into use and the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, any which could adversely affect our results of operations and our business.

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

Our products and product candidates will face substantial competition, whether through the development of safer and more effective alternatives to our products, lower costs to administer than our products or other forms of competition such as more favorable distribution, reimbursement and pricing or formulary and health care provider acceptance. For example, sales of Hextend have been adversely impacted by the availability of other products commonly used in surgery and trauma care and sell at low prices. Ocata, which has been acquired by Astellas Pharma, Inc., is conducting a clinical trial of a RPE cell product designed to treat geographic atrophy. If Astellas' product candidate is proven to be safe and effective, it may be approved and reach the market ahead of OpRegen. Moreover, Astellas' patent portfolio with respect to the manufacture of its RPE products could adversely impact our rights to manufacture OpRegen. In addition, even if our products are approved, physicians, patients and others in the medical community 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.

**We will face risks related to our own manufacturing capabilities and those related to our reliance on third parties to manufacture products, including those related to product acquisition costs, production delays, and supply shortages that could impair our ability to complete the development and commercialization of our product candidates.**

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We do not currently have nor do we plan to acquire the infrastructure or capability to internally manufacture Renevia or our other HyStem products on a clinical or commercial scale. Although we are developing manufacturing capability through Cell Cure for OpRegen in Israel, we will need greater manufacturing capacity if we are to successfully commercialize our products. Unless we can raise the capital required to construct our own commercial scale manufacturing facilities and can develop the expertise to manage and operate a manufacturing facility of our own, we may need to rely on third-party manufacturers to manufacture any products we develop. There is no assurance that we will be able to identify manufacturers on acceptable terms or at all. Regardless of whether we do our own manufacturing or rely on third parties to manufacture products for us, we will face risks related to the manufacture of our products including these risks:

We or any third-party manufacturers might not timely formulate and manufacture our products or produce the quantity and quality required to meet our clinical and commercial needs, if any.

We or any third-party manufacturers may not execute our manufacturing procedures appropriately.

Any third-party manufacturers we engage may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products on a commercial scale.

We or any third-party manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current good manufacturing practices, or cGMP, and other government regulations and corresponding foreign standards. We will not have control over third-party manufacturers' compliance with applicable regulations and standards.

We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates.

We may not obtain licenses for third-party intellectual property rights needed by manufacturers to produce our products.

Third-party manufacturers could breach or terminate their agreements with us.

We or third-party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments.

In addition, we may rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not appropriately conducted and test data are not reliable, patients could be put at risk of serious harm which could result in product liability suits.

If we or any third-party manufacturers we may engage were to encounter any of these difficulties, our ability to provide our product candidates to patients in clinical trials or to the medical market place would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, could require us to either commence new clinical trials at additional expense or terminate clinical trials completely. Each risk could delay our clinical trials, any approval of our product candidates by the FDA, or the commercialization of our product candidates, and could result in higher costs or deprive us of potential product revenue.

**Any cell-based products that receive regulatory approval may be difficult and expensive to manufacture profitably.**

Cell-based products are among the more expensive biological products to manufacture in accordance with cGMP. We do not yet have sufficient information to reliably estimate the cost of commercially manufacturing any of our product candidates. Excessive manufacturing costs could make our product candidates too expensive to compete in the medical market place with alternative products manufactured by our competitors or might result in third party payors such as health insurers and Medicare, declining to cover our products or setting reimbursement levels too low for us to earn a profit from the commercialization of one or more of our products.

**If we do not receive CE Mark approval for Renevia, we may not commercialize Renevia at all.**

To provide our products in other countries we must obtain regulatory approvals and comply with the regulations of those countries, which may differ substantially from those of the U.S. The European Union (EU) requires that manufacturers of medical products obtain the right to affix the CE mark, for compliance with the Medical Device Directive (93/42/EEC), as amended, to their products before selling them in member countries of the EU. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. To obtain the authorization to affix the CE mark to products, a manufacturer must obtain certification that its processes and products meet certain European quality standards.

In March 2018, we submitted a design dossier for CE Mark for the use of Renevia® as a device to aid in transferring a patient's own adipose tissue to treat certain forms of facial lipoatrophy, or fat loss. At time of submission, we anticipated CE Mark approval in the second half of 2018. We have been informed by our European regulatory body of an issue with limited resources and consequently, feedback on our submission has been significantly delayed. We currently expect to receive a final response on our submission in the second half of 2019. Because we have no commercial infrastructure, if we receive a CE Mark for Renevia we intend to seek a commercialization partner in the EU. However, we can give no assurance that we will receive CE Mark approval or secure a commercialization partner for Renevia. If we do not receive approval, we will not be able to commercialize Renevia in member countries of the EU or affiliated countries that accept the CE mark. Based on conversations with the FDA, we received feedback that Renevia would be considered a drug device combination and we would need to conduct a larger clinical development program that can reasonably be supported by the commercial opportunity for Renevia in facial lipoatrophy. Accordingly, if we do not receive CE Mark approval for Renevia, we may not commercialize Renevia at all.

**We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use or misuse of our product candidates harm patients or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.**

We face the risk of incurring liabilities to clinical trial patients if they are injured as a result of their participation in our clinical trials. If any claims are made and if liability can be established, the amount of any liability we or our affiliates may incur, could exceed any insurance coverage in effect, and the amount of the liability could be material to our financial condition.

The use or misuse of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit

or eventual outcome, product liability claims may result in:

impairment of our business reputation;

initiation of investigations by regulators;

withdrawal of clinical trial participants;

costs due to related litigation;

distraction of management's attention from our primary business;

substantial monetary awards to patients or other claimants;

the inability to commercialize our product candidates;

product recalls, withdrawals or labeling, marketing or promotional restrictions; and

decreased demand for our product candidates, if approved for commercial sale.

We believe our current product liability insurance coverage is appropriate in light of our clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to increase our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. Significant damages have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if the amount of damages exceeds our insurance coverage, could adversely affect our results of operations and business.

**Cell Cure has received Israeli government grants for certain of its research and development activities. The terms of these grants may require Cell Cure to seek approvals and to satisfy specified conditions to manufacture products and transfer or license grant-supported technologies outside of Israel. In the context of such approvals, Cell Cure will be required to pay penalties in addition to the repayment of the grants. Such grants are applied for on a yearly basis and may not be available or only partially granted in the future, which would increase our costs.**

Cell Cure has received Israeli government grants for certain of its research and development activities. The terms of these grants require prior approval and the satisfaction of specified conditions to manufacture products and transfer or license technologies outside of Israel.

Under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry 5744-1984), and the regulations, guidelines, rules, procedures and benefit tracks thereunder (collectively, the “Innovation Law”), annual research and development programs that meet specified criteria and are approved by a committee of the IIA are eligible for grants. The grants awarded are typically up to 50% of the project’s expenditures, as determined by the IIA committee and subject to the benefit track under which the grant was awarded. A company that receives a grant from the IIA (a “Grant Recipient”), is typically required to pay royalties to the IIA on income generated from products incorporating know-how developed using such grants (including income derived from services associated with such products) or on all revenues of the Grant Recipient (depending upon the terms of the approval letters issued by the IIA), until 100% of the U.S. dollar-linked grant plus annual LIBOR interest is repaid. In general, the rate of such royalties varies between 3% to 5%.

The obligation to pay royalties is contingent on actual revenues being generated from such products and services or actual revenues being generated by the Grant Recipient in general (as the case may be). In the absence of such revenues, no payment of royalties is required. It should be noted that the restrictions under the Innovation Law will continue to apply even after the repayment of such royalties in full by the Grant Recipient including restrictions on the sale, transfer or licensing to a foreign entity of know-how developed as part of the programs under which the grants were given.

The terms of the grants under the Innovation Law also (generally) require that the products developed as part of the programs under which the grants were given be manufactured in Israel and that the know-how developed thereunder may not be transferred outside of Israel, unless prior written approval is received from the IIA (such approval is not required for the transfer of a portion of the manufacturing capacity which does not exceed, in the aggregate, 10% of the portion declared to be manufactured outside of Israel in the applications for funding (in which case only notification is required), and additional payments are required to be made to IIA). It should be noted that this does not restrict the export of products that incorporate the funded know-how.



The Innovation Law restricts the ability to transfer or license know-how funded by IIA outside of Israel. Transfer of IIA-funded know-how outside of Israel requires prior approval and is subject to approval and payment of a redemption fee to the IIA calculated according to the relevant formulas provided under the Innovation Law. A transfer or license for the purpose of the Innovation Law are generally interpreted very broadly and include, inter alia, any actual sale or assignment of the IIA-funded know-how, any license to further develop or otherwise exploit the IIA-funded know-how or the products resulting from such IIA-funded know-how or any other transaction, which, in essence, constitutes a transfer of the IIA-funded know-how. Generally, a mere license solely to market or distribute products resulting from the IIA-funded know-how would not be deemed a transfer or license for the purpose of the Innovation Law.

Part of Cell Cure's research and development efforts have been financed, partially, through grants that it has received from the IIA and when we acquired our holdings in Cell Cure, we undertook in writing, vis-à-vis the IIA, to abide by, and to ensure the abidance of Cell Cure to, the Innovation Law. We therefore must comply with the requirements of the Innovation Law and related regulations. As of December 31, 2018, we received approximately \$13 million of such grants. The restrictions under the Innovation Law may impair our ability to enter into agreements which involve IIA-funded products or know-how without the approval of IIA. We cannot be certain that any approval of IIA will be obtained on terms that are acceptable to us, or at all. We may not receive the required approvals should we wish to transfer or license IIA-funded know-how, manufacturing and/or development outside of Israel in the future. Furthermore, in the event that we undertake a transaction involving the transfer to a non-Israeli entity of know-how developed with IIA-funding pursuant to a merger or similar transaction, the consideration available to our shareholders may be reduced by the amounts we are required to pay to the IIA. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the Innovation Law may subject Cell Cure to mandatory repayment of grants received by it (together with interest and penalties), as well as expose its directors and management to criminal proceedings. In addition, the IIA may from time to time conduct royalty audits. Further grants may not be approved or reduced in the future, which would increase our costs. IIA approval is not required for the marketing or distribution of products resulting from the IIA-funded research or development in the ordinary course of business.

**Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.**

Cell Cure is our 99% owned subsidiary located in Jerusalem, Israel. OpRegen is currently manufactured at Cell Cure and we anticipate transitioning some or all of the manufacturing of OPC1 and VAC2 to Cell Cure as well. A portion of our OpRegen Phase I/IIa clinical trial has been conducted at sites in Israel. Conducting operations internationally involves a number of risks, including:

difficulty in staffing and managing foreign operations;

failure by us to obtain the appropriate regulatory approvals;

logistics and regulations associated with shipping drug product or patient samples, including infrastructure conditions and transportation delays;

financial risks, such as longer payment cycles and exposure to foreign currency exchange rate fluctuations;

political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;

multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, data and privacy laws, regulatory requirements and other governmental approvals, permits and licenses; and

regulatory and compliance risks that may fall within the purview of the U.S. Foreign Corrupt Practice Act, UK Bribery Act, anti-boycott laws and other anti-corruption laws.

Any of these factors could significantly harm our international operations and, consequently, our results of operations. In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our clinical trial activities.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, production, pricing, reimbursement and marketing of tests, as well as by inter-governmental disputes. Any of these changes could adversely affect our business.

Our success internationally will depend, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in Israel. Failure to manage these and other risks may have a material adverse effect on our operations in Israel and on our business as a whole.

### **Risks Related to our Intellectual Property**

#### **Our intellectual property may be insufficient to protect our products.**

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 have licensed patents and patent applications for certain stem cell technology, hEPC, and hES cell lines, hydrogel technology, and other technology from other companies.

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;

our patents may have terms that are inadequate to protect our competitive position on our products;

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. As an example, Astellas' patent portfolio with respect to the manufacture of its RPE products could adversely impact our rights to manufacture OpRegen. 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.

**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.

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.

**Intellectual property we may develop using grants received from governments are subject to rights maintained by those governments.**

Research and development we perform that is funded by grants from government, and any intellectual property that we create using those grants, is subject to certain rights of the government entities to require that we license or grant rights to the intellectual property developed using government funding in certain circumstances.

**There is no certainty that we will be able to obtain licenses to intellectual property rights owned by third-parties.**

There are no assurances that any of our intellectual property rights will guarantee protection or market exclusivity for our products and product candidates. In such cases, we may need to obtain enabling licenses from third parties to protect our products and product candidates, try to secure market exclusivity or avoid infringing on the intellectual property rights of third parties. If we are unable to fully protect our product candidates or achieve market exclusivity for our products and product candidates, our financial success will be dependent, in part, on our ability to protect and enforce our intellectual property rights, to operate without infringing upon the proprietary rights of others, or, when necessary, our ability to obtain enabling licenses.

**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.

### **Risks Related to our Dependence on Third Parties**

**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 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.

**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 we may undertake for our product candidates. We may also rely on third parties to assist with preclinical development of our product candidates. If we outsource clinical trials, we may not directly control the timing, conduct and expense of our clinical trials. If we enlist third parties to conduct clinical trials and they fail to perform their contractual duties or regulatory obligations or fail to meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to failing 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 obtain regulatory approval for or successfully commercialize our product candidates.

**We have relied on CIRM to fund past clinical trials of OPC1 and we do not know if they will provide additional funding for future studies of OPC1.**

We have received \$14 million of funding from CIRM to support clinical development of OPC1. We intend to apply for additional CIRM grants, however, we cannot provide any assurance that such grants will be awarded. If we are unable to obtain another CIRM grant, we will need to raise funds through other mechanisms to support future clinical studies of OPC1, which may take additional time and effort. If capital is not immediately available, this may force us to amend, delay, or discontinue the clinical trial and development work for OPC1 until funding is secured.

**We may need to rely on marketing partners or contract sales companies.**

If we are able to develop our product candidates and obtain necessary regulatory approvals, we may need to rely on marketing, selling or distributing partner. If we do not partner for commercial services, we will depend on our ability to build our own marketing, selling and distribution capabilities, which would require the investment of significant financial and management resources, or we will need to find collaborative marketing partners, 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 sold our products directly to end users at retail prices through our own sales force. There can be no assurance we will be able to negotiate distribution or sales agreements with third parties on favorable terms to justify our investment in our products or achieve sufficient revenues to support our operations.

### **Risks Pertaining to Our Common Shares**

**Because we are engaged in the development of pharmaceutical and stem cell therapy products, 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.

**The market price of our common shares may decline in the future as a result of the Asterias merger.**

The market price of our common shares may decline in the future as a result of the Asterias merger for a number of reasons, including if the integration of both companies is unsuccessful or if we fail to achieve the perceived benefits of the merger, including financial results, as rapidly as or to the extent anticipated by financial or industry analysts. These factors are, to some extent, beyond our control.

**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.

**Insiders continue to have substantial control over our company, which could limit your ability to influence the outcome of key transactions, including a change of control.**

Our directors, executive officers and their affiliates, in the aggregate, owned approximately 32% of the outstanding shares of our common stock as of December 31, 2018. As a result, these shareholders, if acting together, will be able to influence or control matters requiring approval by our shareholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree, and which may be averse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deter certain public investors from purchasing our common stock and might ultimately affect the market price of our common stock.



**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.

**If we or our subsidiaries issue additional common shares or preferred shares, investors in our common shares may experience dilution of their ownership interests.**

We and our subsidiaries may issue additional common shares or other securities convertible into or exercisable for common shares to raise additional capital or to hire or retain employees or consultants, or in connection with future acquisitions of companies or licenses to technology or rights, or for other business purposes. The future issuance of additional securities may be dilutive to our shareholders and may create downward pressure on the trading price of our common stock.

We are currently authorized to issue an aggregate of 252,000,000 shares of capital stock consisting of 250,000,000 common shares and 2,000,000 “blank check” preferred shares, which means we may issue, without stockholder approval, one or more series of preferred stock having such designation, powers, privileges, preferences, including preferences over our common stock respecting dividends and distributions, terms of redemption and relative participation, optional, or other rights, if any, of the shares of each such series of preferred stock and any qualifications, limitations or restrictions thereof, as our board of directors may determine. The terms of one or more series of preferred stock could dilute the voting power or reduce the value of our common stock. 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 impact on our ownership of the subsidiaries.

As of December 31, 2018, we had 127,135,774 common shares outstanding, 13,867,000 common shares reserved for issuance upon the exercise of outstanding options under our employee stock option plans; and 402,000 common shares reserved for issuance upon the lapse of restricted stock units (RSUs) under our equity incentive plan.

The operation of some of our subsidiaries has been financed in part through the sale of shares of capital stock and warrants to purchase securities of those subsidiaries to private investors. Future sales of such securities by our subsidiaries could reduce our ownership interest in the applicable subsidiary, and correspondingly dilute our shareholder's ownership interests in our consolidated enterprise. Certain of our subsidiaries also have their own stock option plans and the exercise of stock options or the sale of restricted stock under those plans would also reduce our ownership interest in the applicable subsidiary, with a resulting dilutive effect on the ownership interest of our shareholders in our consolidated enterprise.

**The market price of our common shares could be impacted by the terms of financings by our subsidiaries.**

The operation of some of our subsidiaries has been financed in part through the sale of shares of capital stock and warrants to purchase securities of those subsidiaries to private investors. The prices at which our subsidiaries may sell shares of their capital stock in the future 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.

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

Because we use the equity method of accounting for the common stock of OncoCyte that we hold at fair value, we will recognize gain or loss to the extent that the market value of OncoCyte common stock changes from calendar quarter to calendar quarter, regardless of whether we sell any of those shares.

## **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None

## **ITEM 2. PROPERTIES**

### **Generally**

In general, we believe that our properties are well-maintained, adequate and suitable for their current requirements and for our operations in the foreseeable future. See the Notes to Consolidated Financial Statements – Note 15. Commitments and Contingencies included elsewhere in this Report.

### **BioTime Facilities**

Our principal offices and laboratory facilities comprise 30,795 square feet in two buildings in Alameda, California. AgeX, ReCyte Therapeutics, OrthoCyte, and OncoCyte share this space with us and it is where OncoCyte plans to operate its CLIA lab.

### **Cell Cure Facilities**

Cell Cure leases 728.5 square meters (approximately 7,842 square feet) of office and laboratory space in the Bio Park on the campus of the Hadassah University Hospital in Jerusalem, Israel under a lease that expires on December 31, 2020, with two options to extend the term for 5 years each.

In January 2018, Cell Cure entered into another lease for an additional 934 square meters (approximately 10,054 square feet) of office space in the same facility in Jerusalem, Israel under a lease that expires on December 31, 2025, with two options to extend the lease for 5 years each. The term of this lease commenced on April 1, 2018 and includes a leasehold improvement construction allowance of up to NIS 4,000,000 (approximately up to \$1.1 million) from the landlord. The leasehold improvements were substantially completed by December 31, 2018 and the construction allowance was fully utilized.

### **ITEM 3. LEGAL PROCEEDINGS**

From time to time, we are subject to legal proceedings and claims in the ordinary course of business. While management presently believes that the ultimate outcome of these proceedings, individually and in the aggregate, will not materially harm our financial position, cash flows, or overall trends in results of operations, legal proceedings are subject to inherent uncertainties, and unfavorable rulings or outcomes could occur that have individually or in aggregate, a material adverse effect on our business, financial condition or operating results. Except as described below, we are not currently subject to any pending material litigation, other than ordinary routine litigation incidental to our business, as described above.

On February 19, 2019, a putative class action lawsuit relating to the Asterias acquisition was filed on behalf of Asterias shareholders in the Superior Court of the State of California in the County of Alameda against, among other parties, Asterias, the members of Asterias' board of directors, BioTime, Neal Bradsher, Broadwood Capital, Inc. and Broadwood Capital Partners, L.P. The lawsuit asserts claims for breach of fiduciary duty and aiding and abetting breach of fiduciary duty, alleging that the consideration Asterias shareholders are to receive in the merger is unfair, the merger is the product of an unfair process, and the joint proxy statement omits certain allegedly material information. The complaint seeks, injunctive relief or rescissory damages and an award of plaintiffs' expenses and attorneys' fees. The defendants specifically deny all allegations in the litigation, including that any additional disclosure was or is required and intend to defend it vigorously. To moot the disclosure claims in the complaint, Asterias and BioTime made supplemental disclosures to the joint proxy statement relating to the merger.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## **PART II**

### **ITEM MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, 5. AND ISSUER PURCHASES OF EQUITY SECURITIES**

#### **Market Information**

Our common stock trades on the NYSE American and on the Tel Aviv Stock Exchange under the ticker symbol BTX.

#### **Holdings**

As of February 15, 2019, there were 16,538 holders of the common shares based on the share position listing.

#### **Dividend Policy**

We have not paid dividends on our common stock. We currently intend to retain any earnings for use in the operations of our business. We, therefore, do not anticipate paying cash dividends on our common stock in the foreseeable future.

#### **Recent Sales of Unregistered Securities**

Except as previously reported in our quarterly reports on Form 10-Q and current reports on Form 8-K filed with the Securities and Exchange Commission ("SEC"), during the year ended December 31, 2018, there were no unregistered sales of equity securities by us during the year ended December 31, 2018.

### **ITEM 6. SELECTED FINANCIAL DATA**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Accordingly, we are not required to provide the information required by this item in this Report.





## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the two-year period ended December 31, 2018, 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, 2018 as compared to the year ended December 31, 2017. This discussion should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Report. 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."*

### **Overview**

BioTime is a clinical-stage biotechnology company developing new cellular therapies for degenerative retinal diseases, neurological conditions associated with demyelination, and aiding the body in detecting and combating cancer. BioTime's programs are based on its proprietary cell-based therapy platform and associated development and manufacturing capabilities. With this platform BioTime develops and manufactures specialized, terminally-differentiated human cells from our pluripotent and progenitor cell starting materials. These differentiated cells are developed either to replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury, or administered as a means of helping the body mount an effective immune response to cancer.

BioTime has three cell therapy programs in clinical development:

*OpRegen*<sup>®</sup>, a retinal pigment epithelium cell replacement therapy currently in a Phase I/IIa multicenter clinical trial for the treatment of advanced dry-age-related macular degeneration ("dry-AMD") with geographic atrophy. There currently are no therapies approved by the U.S. Food and Drug Administration ("FDA") for dry-AMD, which accounts for approximately 90% of all AMD cases and is the leading cause of blindness in people over the age of 60.

*OPC1*, an oligodendrocyte progenitor cell therapy currently in a Phase I/IIa multicenter clinical trial for acute spinal cord injuries ("SCI"). This clinical trial has been partially funded by the California Institute for Regenerative Medicine ("CIRM").

*VAC2*, an allogeneic (non-patient-specific or "off-the-shelf") cancer immunotherapy of antigen-presenting dendritic cells currently in a Phase I clinical trial in non-small cell lung cancer. This clinical trial is being funded and

conducted by Cancer Research UK (“CRUK”), the world’s largest independent cancer research charity.

BioTime also has cell/drug delivery programs that are based upon its proprietary *HyStem*<sup>®</sup> cell and drug delivery matrix technology. *HyStem*<sup>®</sup> was designed to support the formulation, transfer, retention, and engraftment of cellular therapies.

BioTime completed its merger with Asterias Biotherapeutics, Inc. on March 8, 2019, which incorporated OPC1 and VAC2 into its cell therapy product portfolio.

BioTime also has equity holdings in two publicly traded companies, OncoCyte Corporation (“OncoCyte”) (approximately 28% ownership) and AgeX Therapeutics, Inc. (“AgeX”) (approximately 5% ownership), which BioTime founded and, in prior years, were majority-owned and consolidated subsidiaries. OncoCyte (NYSE American: OCX) is developing confirmatory diagnostic tests for lung cancer utilizing novel liquid biopsy technology and AgeX is focused on the development of early-stage programs relating to cell immortality, regenerative biology, aging, and age-related diseases.

### **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 and financing 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* – In accordance with ASU No. 2014-15 *Presentation of Financial Statements – Going Concern*, we 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.

*Adoption of ASU 2014-09, Revenues from Contracts with Customers (Topic 606)* – During May 2014, the FASB issued ASU 2014-09 (“Topic 606”) *Revenue from Contracts with Customers* which supersedes the revenue recognition requirements in Topic 605 *Revenue Recognition* (“Topic 605”). Topic 606 describes principles an entity must apply to measure and recognize revenue and the related cash flows, using the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. Topic 606 core principle is that it requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

BioTime adopted Topic 606 as of January 1, 2018 using the modified retrospective transition method applied to those contracts which were not completed as of the adoption date. Results for reporting periods beginning on January 1, 2018 and thereafter are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with BioTime’s historic revenue recognition accounting under Topic 605.

On January 1, 2018, the adoption and application of Topic 606 resulted in an immaterial cumulative effect adjustment of BioTime’s beginning consolidated accumulated deficit balance. In the applicable paragraphs below, BioTime has summarized its revenue recognition policies for its various revenue sources in accordance with Topic 606.

*Research and development contracts with customers* – In its agreements with customers, BioTime’s performance obligations of research and development are completed as services are performed and control passes to the customer, and accordingly revenues are recognized over time. BioTime generally receives a fee at the inception of an agreement, with variable fees, if any, tied to certain milestones, if achieved. BioTime estimates this variable consideration using a

single most likely amount. Based on historical experience, there has been no variable consideration related to milestones included in the transaction price due to the significant uncertainty of achieving contract milestones and milestones not being met. If a milestone is met, subsequent changes in the single most likely amount may produce a different variable consideration, and BioTime will allocate any subsequent changes in the transaction price on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation will be recognized as revenue in the period in which the transaction price changes with respect to variable consideration, which could result in a reduction of revenue. Contracts of this kind are typically for a term greater than one year. For each of the years ended December 31, 2018 and 2017, BioTime recognized \$308,000 for such services included in the consolidated royalties from product sales and license fees. There were no deferred revenues related to unsatisfied performance obligations in the consolidated balance sheet as of December 31, 2018. As of December 31, 2018, BioTime had not met any milestones that would require adjustment of the transaction price.

*Royalties from product sales and license fees* – BioTime’s performance obligations in agreements with certain customers is to provide a license to allow customers to make, import and sell company licensed products or methods for pre-clinical studies and commercial use. Customers pay a combination of a license issue fee paid up front and a sales-based royalty, if any, in some cases with yearly minimums. The transaction price is deemed to be the license issue fee stated in the contract. The license offered by BioTime is a functional license with significant standalone functionality and provides customers with the right to use BioTime’s intellectual property. This allows BioTime to recognize revenue on the license issue fee at a point in time at the beginning of the contract, which is when the customer begins to have use of the license. Variable consideration related to sales-based royalties is recognized only when (or as) the later of one or more of the following events occur: (a) a sale or usage occurs, or (b) the performance obligation to which some, or all, of the sales-based or usage-based royalty that has been allocated and has been satisfied or partially satisfied. Due to the contract termination clauses, BioTime does not expect to receive all of the minimum royalty payments throughout the term of the agreements. Therefore, BioTime fully constrains recognition of the minimum royalty payments as revenues until its customers are obligated to pay, which is generally within 60 days prior to the beginning of each year the minimum royalty payments are due. For the years ended December 31, 2018 and 2017, royalty revenues were immaterial.

*Sale of research products and services* – Revenues from the sale of research products and services are primarily derived from the sale of hydrogels and stem cell products for research use and are recognized when earned. These revenues are recognized at a point-in-time when control of the product transfers to the customer, which is typically upon shipment to the customer from the Alameda facility. Cost of sales from the sale of research products include direct and indirect overhead expenses incurred to purchase and manufacture those products, including lab supplies, personnel costs, freight, and royalties paid, if any, in accordance with the terms of applicable licensing agreements for those products.

*Subscription and advertisement revenues* – LifeMap Sciences, now a direct majority-owned subsidiary of AgeX, sells subscription-based products, including research databases and software tools, for biomedical, gene, disease, and stem cell research. LifeMap Sciences sells these subscriptions primarily through the internet to biotech and pharmaceutical companies worldwide. LifeMap Sciences' principal subscription product is the GeneCard® Suite, which includes the GeneCards® human gene database, and the MalaCards™ human disease database.

LifeMap Sciences' performance obligations for subscriptions include a license of intellectual property related to its genetic information packages and premium genetic information tools. These licenses are deemed functional licenses that provide customers with a "right to access" to LifeMap Sciences' intellectual property during the subscription period and, accordingly, revenue is recognized over a period of time, which is generally the subscription period. Payments are typically received at the beginning of a subscription period and revenue is recognized according to the type of subscription sold.

For subscription contracts in which the subscription term commences before a payment is due, LifeMap Sciences records an accounts receivable as the subscription is earned over time and bills the customer according to the contract terms. LifeMap Sciences continuously monitors collections and payments from customers and maintains a provision for estimated credit losses and uncollectible accounts based upon its historical experience and any specific customer collection issues that have been identified. Amounts determined to be uncollectible are written off against the allowance for doubtful accounts. LifeMap Sciences has not historically provided significant discounts, credits, concessions, or other incentives from the stated price in the contract as the prices are offered on a fixed fee basis for the type of subscription package being purchased. LifeMap Sciences may issue refunds only if the packages cease to be available for reasons beyond its control. In such an event, the customer will get a refund on a pro-rata basis. Using the most likely amount method for estimating refunds under Topic 606, including historical experience, LifeMap Sciences determined that the single most likely amount of variable consideration for refunds is immaterial as LifeMap Sciences does not expect to pay any refunds. Both the customer and LifeMap Sciences expect the subscription packages to be available during the entire subscription period, and LifeMap Sciences has not experienced any significant issues with the availability of the product and has not issued any material refunds.

LifeMap Sciences performance obligations for advertising are overall advertising services and represent a series of distinct services. Contracts are typically less than a year in duration and the fees charged may include a combination of fixed and variable fees with the variable fees tied to click throughs to the customer's products on their website. LifeMap Sciences allocates the variable consideration to each month the click through services occur and allocates the

annual fee to the performance obligation period of the initial term of the contract because those amounts correspond to the value provided to the customer each month. For click-through advertising services, at the time the variable compensation is known and determinable, the service has been rendered. Revenue is recognized at that time. The annual fee is recognized over the initial subscription period because this is a service and the customer simultaneously receives and consumes the benefit of LifeMap Sciences' performance.

LifeMap Sciences deferred subscription revenues primarily represent subscriptions for which cash payment has been received for the subscription term, but the subscription term has not been completed as of the balance sheet date reported. Beginning on August 30, 2018, there are no revenues or cost of sales recorded from subscription and advertisement products because of the AgeX Deconsolidation. The LifeMap Sciences revenues presented for the year ended December 31, 2018 are for revenues earned through August 29, 2018, the date immediately preceding the AgeX Deconsolidation.

*Grant revenues* – In applying the provisions of Topic 606, BioTime has determined that government grants are out of the scope of Topic 606 because the government entities do not meet the definition of a “customer”, as defined by Topic 606, as there is not considered to be a transfer of control of good or services to the government entities funding the grant. BioTime has, and will continue to, account for grants received to perform research and development services in accordance with ASC 730-20, *Research and Development Arrangements*, which requires an assessment, at the inception of the grant, of whether the grant is a liability or a contract to perform research and development services for others. If BioTime or a subsidiary receiving the grant is obligated to repay the grant funds to the grantor regardless of the outcome of the research and development activities, then BioTime is required to estimate and recognize that liability. Alternatively, if BioTime or a subsidiary receiving the grant is not required to repay, or if it is required to repay the grant funds only if the research and development activities are successful, then the grant agreement is accounted for as a contract to perform research and development services for others, in which case, grant revenue is recognized when the related research and development expenses are incurred.

Deferred grant revenues represent grant funds received from the governmental funding agencies for which the allowable expenses have not yet been incurred as of the balance sheet date reported.

*Arrangements with multiple performance obligations* – BioTime’s contracts with customers may include multiple performance obligations. For such arrangements, BioTime allocates revenue to each performance obligation based on its relative standalone selling price. BioTime generally determines or estimates standalone selling prices based on the prices charged, or that would be charged, to customers for that product or service. As of, and for the year ended, December 31, 2018, BioTime did not have significant arrangements with multiple performance obligations.

*Equity method accounting for Asterias and OncoCyte, 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 nonoperating gain or loss from equity method investments included in other income and expenses, net. See Notes 6 and 7 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 compensation and related benefits, stock-based compensation, consulting fees, research and laboratory fees, rent of research facilities, amortization of intangible assets, 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. Upon adoption of ASU 2016-09 on January 1, 2017, forfeitures are accounted for as they occur instead of based on the number of awards that were expected to vest prior to adoption of ASU 2016-09. Based on the nature and timing of our grants, straight line expense attribution of stock-based compensation for the entire award and the relatively low forfeiture rates on BioTime’s experience, the impact of adoption of ASU 2016-09 pertaining to forfeitures was not material to our consolidated financial statements. We utilize the Black-Scholes 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.

Certain of our privately-held formerly consolidated subsidiaries have their own share-based compensation plans. For share-based compensation awards granted by those privately-held consolidated subsidiaries under their respective equity plans, which are included in our consolidated financial statements and results of operations for the years presented, we determined 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 formerly 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.



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.

*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. If our assumptions, and consequently the 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 financial statements. We recognize accrued interest and penalties related to unrecognized tax benefits, if any, as income tax expense, however, no amounts were accrued for the payment of interest and penalties as of December 31, 2018 and 2017.

On December 22, 2017, the United States enacted major federal tax reform legislation, Public Law No. 115-97, commonly referred to as the 2017 Tax Cuts and Jobs Act (“2017 Tax Act”), which enacted a broad range of changes to the Internal Revenue Code. Changes to taxes on corporations impacted by the 2017 Tax Act include, among others, lowering the U.S. federal tax rates to a 21% flat tax rate, elimination of the corporate alternative minimum tax (“AMT”), imposing additional limitations on the deductibility of interest and net operating losses, allowing any net operating loss (“NOLs”) generated in tax years ending after December 31, 2017 to be carried forward indefinitely and generally repealing carrybacks, reducing the maximum deduction for NOL carryforwards arising in tax years beginning after 2017 to a percentage of the taxpayer's taxable income, and allowing for the expensing of certain capital expenditures. The 2017 Tax Act also puts into effect a number of changes impacting operations outside of the United States including, but not limited to, the imposition of a one-time tax “deemed repatriation” on accumulated offshore earnings not previously subject to U.S. tax, and shifts the U.S. taxation of multinational corporations from a worldwide system of taxation to a territorial system. ASC 740 requires the effects of changes in tax rates and laws on deferred tax balances (including the effects of the one-time transition tax) to be recognized in the period in which the legislation is enacted.

For 2017, LifeMap Sciences included a deemed repatriation of \$227,000 in accumulated foreign earnings not previously subject to U.S. tax in federal income from LifeMap Sciences Ltd. The federal taxable income was offset by

the LifeMap Sciences' net operating loss carryforwards resulting in no federal income tax due.

Beginning in 2018, the 2017 Tax Act subjects a U.S. shareholder to tax on Global Intangible Low Tax Income ("GILTI") earned by certain foreign subsidiaries. In general, GILTI is the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets. The provision further allows a deduction of 50 percent of GILTI; however, this deduction is limited by the company's pre-GILTI U.S. income. For 2018, we incurred a net loss from foreign activity, accordingly there was no GILTI inclusion in U.S. income. Based on current interpretations under ASC 740, an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. We have elected to account for GILTI as a current period expense when incurred.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to provide guidance for companies that are not able to complete their accounting for the income tax effects of the 2017 Tax Act in the period of enactment. SAB 118 allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We applied the guidance in SAB 118 when accounting for the enactment-date effects of the Tax Act in 2017 and throughout 2018. At December 31, 2018, we have completed our accounting for all the enactment-date income tax effects of the Tax Act. ASC 740 requires the effects of changes in tax rates and laws on deferred tax balances (including the effects of the one-time transition tax) to be recognized in the period in which the legislation is enacted (see Note 14 to our consolidated financial statements included elsewhere in this Report).

*Principles of consolidation* – Our consolidated financial statements include the accounts of our wholly-owned and majority-owned subsidiaries. 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.

As further discussed in Notes 3 and 4 to the consolidated financial statements included elsewhere in this Report, on August 30, 2018, we consummated the sale of AgeX Shares to Juvenescence. Prior to the Juvenescence Transaction, Juvenescence owned 5.6% of AgeX's issued and outstanding common stock. Upon completion of the Juvenescence Transaction, our ownership in AgeX decreased from 80.4% to 40.2% of AgeX's issued and outstanding shares of common stock, and Juvenescence's ownership in AgeX increased from 5.6% to 45.8% of AgeX's issued and outstanding shares of common stock. As a result of the consummation of the Juvenescence Transaction on August 30, 2018, AgeX is no longer our subsidiary and, as of that date, we experienced a "loss of control" of AgeX, as defined by 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 of a 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 representing a majority of the voting power of the subsidiary's voting securities. All of these loss-of-control factors were present with respect to our ownership interest in AgeX as of August 30, 2018. Accordingly, we have deconsolidated AgeX's consolidated financial statements and consolidated results from our consolidated financial statements.

As further discussed in Notes 5 and 6 to the consolidated financial statements included elsewhere in this Report, 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. Accordingly, since February 17, 2017, we have accounted 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 is reflected on our consolidated balance sheet and changes in the market value of those shares are reflected in our consolidated statements of operations, allowing our shareholders to evaluate the value of the OncoCyte portion of our business.

As further discussed in Notes 5 and 7 to our consolidated financial statements included elsewhere in this Report, effective May 13, 2016, we deconsolidated Asterias financial statements and results of operations due to our "loss of control" of Asterias 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 presented in this Report, the market value of the Asterias common stock we hold is reflected on our consolidated balance sheet and changes in the market value of those shares are 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 19 to our consolidated financial statements included elsewhere in this Report, effective March 8, 2019, we completed the Asterias Merger in which we acquired the approximate 61% remaining ownership interest in Asterias in a stock-for-stock acquisition. As of March 8, 2019, Asterias is our wholly-owned subsidiary, Asterias ceased to exist as a public company, and we will consolidate Asterias' operations and results with our operations and results beginning on that date.

## **Results of Operations**

*Comparison of Years Ended December 31, 2018 and 2017**Revenues*

The following table shows our revenues for the years ended December 31, 2018 and 2017 (amounts in thousands).

	<b>Year Ended</b>		<b>\$</b>	<b>%</b>
	<b>December 31,</b>		<b>Increase/</b>	<b>Increase/</b>
	<b>2018</b>	<b>2017</b>	<b>(Decrease)</b>	<b>(Decrease)</b>
Grant revenue	\$3,572	\$1,666	\$ 1,906	114.4%
Royalties from product sales and license fees	392	389	3	0.8 %
Subscription and advertising revenues	691	1,395	(704)	(50.5 %)
Sale of research products and services	333	8	325	*%
Total revenues	4,988	3,458	1,530	44.2 %
Cost of sales	(302)	(168)	134	79.8 %
Gross profit	\$4,686	\$3,290	\$ 1,396	42.4 %

\*Not meaningful.

The \$1.5 million increase in our total revenues year-over-year was primarily due to a \$1.9 million increase in our grant revenues, partially offset by the \$0.7 million decrease in our subscription and advertising revenues.

Our subscription and advertising revenues, including certain service revenues, were generated entirely by LifeMap Sciences, AgeX's majority-owned subsidiary and are included in our consolidated revenues for periods through August 29, 2018, the date before the AgeX Deconsolidation. The decrease in those revenues is due to the AgeX Deconsolidation on August 30, 2018. Due to the AgeX Deconsolidation, we do not expect to earn subscription and advertising revenues in future accounting periods.

Revenues from the sale of research products and services are primarily derived from service revenues and the sale of hydrogels and stem cell products, which we commenced selling again during the year ended December 31, 2018. Revenues were insignificant during 2017 principally as a result of the reduction of operations at LifeMap Solutions. During July 2017, LifeMap Solutions ceased conducting its mobile health software development application business and was dissolved on February 9, 2018.

The \$0.1 million increase in cost of sales year-over-year was mainly attributable to an increase in the royalty rate effective January 1, 2018 for LifeMap Sciences, timing of cash received, and the related royalty obligation incurred for periods through August 29, 2018, and cost of sales incurred from the sale of hydrogels and stem cell products. Due to the AgeX Deconsolidation, we do not expect to incur costs of sales in the future with respect to subscription and advertising revenues or with respect to sales of research products by AgeX.

### *Operating Expenses*

The following table shows our operating expenses for the years ended December 31, 2018 and 2017 (in thousands).

	<b>Year Ended December</b>		<b>\$</b>	<b>%</b>
	<b>2018</b>	<b>2017</b>	<b>Increase/ (Decrease)</b>	<b>Increase/ Decrease</b>
Research and development expenses	\$21,755 <sup>(1)</sup>	\$24,024 <sup>(2)</sup>	\$ (2,269)	(9.4%)
General and administrative expenses	24,726 <sup>(3)</sup>	19,922 <sup>(4)</sup>	4,804	24.1%

(1) Includes \$4.6 million of AgeX research and development expenses incurred before the AgeX Deconsolidation.

(2) Includes \$798,000 of OncoCyte research and development expenses incurred before the OncoCyte Deconsolidation.

(3) Includes \$3.1 million of AgeX general and administrative expenses incurred before the AgeX Deconsolidation.

(4) Includes \$590,000 of OncoCyte general and administrative expenses incurred before the OncoCyte Deconsolidation.

*Research and development expenses*

The \$2.3 million decrease in our research and development expenses year-over-year was primarily attributable to: a decrease of \$1.5 million in AgeX related programs, including LifeMap Sciences, due to the AgeX Deconsolidation on August 30, 2018; a decrease of \$0.3 million in BioTime related program expenses, primarily related to the completion of the Renevia® clinical trial in 2018; a decrease of \$0.8 million from the nonrecognition of OncoCyte research and development expenses incurred after February 17, 2017 as a result of the OncoCyte Deconsolidation; and a decrease of \$0.5 million in LifeMap Solutions expenses resulting from the cessation of its mobile health software development application business in July 2017. The decreases were partially offset by a nonrecurring \$0.8 million expense incurred by AgeX on March 23, 2018 with respect to certain acquired in-process research and development assets that have no alternative future uses.

The following table shows the amounts and percentages of our total research and development expenses of \$21.8 million and \$24.0 million allocated to our primary research and development programs during the years ended December 31, 2018 and 2017, respectively (amounts in thousands).

Company	Program	Year Ended December 31,			
		Amount <sup>(1)</sup>		Percent of Total	
		2018	2017	2018	2017
BioTime and subsidiaries other than AgeX <sup>(2)</sup>	<i>OpRegen<sup>®</sup> and Renevia<sup>®</sup> and other HyStem<sup>®</sup> products and PureStem<sup>®</sup> progenitor cell lines for orthopedic applications</i>	\$17,158	\$17,456	78.9%	72.7%
AgeX including ReCyte <sup>(3)</sup>	<i>PureStem<sup>®</sup> progenitor cell lines, brown adipose fat, iTR technology, and pre-clinical cardiovascular therapy research and development</i>	2,779	3,736	12.8%	15.6%
AgeX <sup>(4)</sup>	Acquired in-process research and development	800	-	3.7%	-
LifeMap Sciences <sup>(5)</sup>	Biomedical, gene, and disease databases and tools	1,018	1,548	4.6%	6.4%
LifeMap Solutions <sup>(6)</sup>	Mobile health software application	-	486	%	2.0%
OncoCyte <sup>(7)</sup>	Cancer diagnostics	-	798	%	3.3%
Total research and development expenses		\$21,755	\$24,024	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) BioTime includes Cell Cure, ESI, and OrthoCyte.

(3) Although AgeX was capitalized during August 2017 by the contribution of assets from BioTime and cash from outside investors, for comparative purposes in the table above, AgeX related research and development expenses that were previously included in BioTime have been reclassified to AgeX for 2017. Research and development expenses shown for 2018 are through August 29, 2018, the date prior to the AgeX Deconsolidation.

(4) On March 23, 2018, AgeX purchased certain in-process research and development assets, primarily related to stem cell derived cardiomyocytes (heart muscle cells) to be developed by AgeX, for a total cash consideration of \$800,000. The transaction was considered an asset acquisition rather than a business combination. Accordingly, the \$800,000 was expensed on the acquisition date as acquired in-process research and development as those assets have no alternative future use.

(5) LifeMap Sciences is a subsidiary of AgeX. Research and development expenses shown for the periods presented in 2018 are through August 29, 2018, the date prior to the AgeX Deconsolidation.

(6) LifeMap Solutions ceased conducting its mobile health software application business during July 2017 and was dissolved on February 9, 2018.

(7) Includes the period from January 1, 2017 through February 16, 2017, the date prior to the OncoCyte Deconsolidation.

*General and administrative 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, costs of patent applications, prosecution and maintenance, stock exchange-related costs, depreciation expense, marketing costs, board fees, legal and accounting costs, and other miscellaneous expenses which are allocated to general and administrative expense.

The following table shows the amount and percentages of our total general and administrative expenses of \$24.7 million and \$19.9 million incurred and allocated to BioTime and our subsidiaries during the years ended December 31, 2018 and 2017, respectively (amounts in thousands).



Company	Year Ended December 31,			
	Amount <sup>(1)</sup>		Percent	
	2018	2017	2018	2017
BioTime and subsidiaries other than AgeX <sup>(2)</sup>	\$21,596	\$15,061	87.3%	75.6%
AgeX including ReCyte <sup>(3)</sup>	2,584	2,873	10.5%	14.4%
LifeMap Sciences <sup>(4)</sup>	546	563	2.2%	2.8%
LifeMap Solutions <sup>(5)</sup>	-	835	-	4.2%
OncoCyte <sup>(6)</sup>	-	590	-	3.0%
Total general and administrative expenses	\$24,726	\$19,922	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) BioTime includes Cell Cure, ESI, and OrthoCyte.

Although AgeX was capitalized during August 2017 by the contribution of assets from BioTime and cash from outside investors, for comparative purposes in the tables above, AgeX related general and administrative expenses (3) that were previously included in BioTime have been reclassified to AgeX for the 2017 periods presented. General and administrative expenses shown for the periods presented in 2018 are through August 29, 2018, the date prior to the AgeX Deconsolidation.

(4) LifeMap Sciences is a subsidiary of AgeX. General and administrative expenses shown for the periods presented in 2018 are through August 29, 2018, the date prior to the AgeX Deconsolidation.

(5) LifeMap Solutions ceased conducting its mobile health software application business during July 2017 and was dissolved on February 9, 2018.

(6) Includes the period from January 1, 2017 through February 16, 2017, the date prior to the OncoCyte Deconsolidation.

The \$4.8 million increase in general and administrative expense year-over-year was primarily attributable to: a \$2.3 million increase due to management transition and other compensation related costs, including hiring costs for a new chief executive officer during September 2018; a \$2.1 million increase in legal, audit and compliance costs related to the AgeX Distribution; and a \$1.5 million increase in noncash stock-based compensation expense due to increases in equity award grants. These increases were offset to some extent by a \$0.3 million decrease in AgeX related costs, including LifeMap Sciences, due to the AgeX Deconsolidation, and a \$1.4 million decrease in combined general and administrative expenses related to OncoCyte and LifeMap Solutions, shown in the table above.

### ***Other income and expenses, net***

The following table shows the amount of other income and expenses, net, during the year ended December 31, 2018 and 2017 (in thousands):

	Year Ended	
	December 31,	
	2018	2017
Other income/(expenses), net		
Interest income (expense), net	\$711	\$(692)
Gain on sale of equity method investment in Ascendance	3,215	-
Gain on sale of AgeX shares and deconsolidation of AgeX	78,511	-
Gain on deconsolidation of OncoCyte	-	71,697
Loss on equity method investment in OncoCyte at fair value	(47,985)	(2,935)
Loss on equity method investment in Asterias at fair value	(35,449)	(51,107)
Loss on equity method investment in AgeX at fair value	(4,181)	-
Unrealized gain on marketable equity securities	1,158	-
Loss on extinguishment of related party convertible debt	-	(2,799)
Other income (expenses), net	(1,315)	1,449
Total other income (expenses), net	\$(5,335)	\$15,613

*Interest income and expense, net* – During 2018, we incurred \$0.2 million of interest expense, which was primarily related to interest on amortization of our lease liability, offset by \$0.9 million of interest income principally earned from our Juvenescence promissory note and our money market funds. During 2017, we incurred \$0.8 million of interest expense, which was primarily noncash interest expense on amortization of a discount on related party convertible debt, offset by \$0.1 million of interest income. Interest income is primarily attributed to interest earned on cash and cash equivalents balances held in interest bearing accounts during the respective years.

*Gain on sale of equity method investment in Ascendance* - On March 23, 2018, Ascendance was acquired by a third party in a merger through which AgeX received approximately \$3.2 million in cash for its shares of Ascendance common stock. AgeX recognized a \$3.2 million gain on the sale of its equity method investment in Ascendance, which is included in other income and expenses, net, for the year ended December 31, 2018.

*Gain on sale of our significant ownership interest in, and deconsolidation, of AgeX* – On August 30, 2018, we sold 14.4 million shares of our AgeX common stock to Juvenescence Limited for \$3.00 per share, or aggregate consideration of \$43.2 million. Upon completion of the sale, our percentage ownership in AgeX decreased from 80.4% to 40.2% and Juvenescence’s percentage ownership in AgeX increased from 5.6% to 45.8%. As a result, on August 30, 2018, we experienced a loss of control of AgeX in accordance with GAAP and deconsolidated AgeX’s consolidated financial statements and consolidated results from ours. In connection with this transaction, we recorded a gain on deconsolidation of \$78.5 million, which includes a gain on the sale of the AgeX shares of \$39.2 million, during the year ended December 31, 2018, included in other income and expenses, net.

*Unrealized loss on AgeX Shares* – Beginning on August 30, 2018 through November 28, 2018, the completion of the AgeX Distribution, we held 40.2% of AgeX’s outstanding shares of common stock and accounted for those shares using the equity method of accounting at fair value. For the period from August 30, 2018 through November 28, 2018, we recorded an unrealized loss of \$4.2 million due to the decrease in the AgeX stock price from August 30, 2018 to November 28, 2018, the date on which we completed the AgeX Distribution (see Note 4 to our consolidated financial statements included elsewhere in this Report). Immediately following the distribution, we owned 1.7 million shares of AgeX common stock, all of which we still own, and which represents approximately 4.8% of AgeX’s outstanding common stock as of December 31, 2018 and which shares we hold as marketable equity securities.

*Gain on deconsolidation of OncoCyte* – During the year ended December 31, 2017, we recorded a gain of \$71.7 million in connection with the OncoCyte Deconsolidation on February 17, 2017.

*Unrealized loss on OncoCyte Shares* – We own 14.7 million shares of common stock of OncoCyte, or approximately 36.1% of the OncoCyte common stock outstanding as of December 31, 2018. We elected to account for our shares in OncoCyte at fair value using the equity method of accounting beginning on February 17, 2017, the date of the OncoCyte Deconsolidation. Our OncoCyte shares had a fair value of \$20.3 million and \$68.2 million as of December 31, 2018 and December 31, 2017, respectively, based on the \$1.38 per share and \$4.65 per share closing prices of OncoCyte common stock on the NYSE American on those respective dates, resulting in an unrealized loss of \$47.9 million recorded in 2018. Our OncoCyte shares had a fair value of \$68.2 million and \$71.2 million as of as of December 31, 2017 and February 17, 2017, respectively, based on the \$4.65 per share and \$4.85 per share closing prices of OncoCyte common stock on the NYSE American on those respective dates, resulting in an unrealized loss of \$2.9 million recorded in 2017.

*Unrealized loss on Asterias Shares* – We own 21.7 million shares of common stock of Asterias, or approximately 39.1% of Asterias outstanding common stock as of December 31, 2018. 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 \$13.5 million and \$48.9 million as of December 31, 2018 and December 31, 2017, respectively, based on the \$0.62 per share and \$2.25 per share closing prices of Asterias common stock on the NYSE American on those respective dates, resulting in an unrealized loss of \$35.4 million recorded in 2018. Our Asterias shares had a fair value of \$48.9 million and \$100.0 million as of December 31, 2017 and December 31, 2016, respectively, based on the \$2.25 per share and \$4.60 per share closing prices of Asterias common stock on the NYSE American on those respective dates, resulting in an unrealized loss of \$51.1 million recorded in 2017.

*Unrealized gain on marketable equity securities* – We account for the shares we hold in foreign equity securities in HBL and, the AgeX shares of common stock we hold beginning on November 28, 2018, as marketable equity securities, carried at fair market value on our consolidated balance sheet, with changes in fair market value included in other income and expenses, net, in our consolidated statements of operations. Prior to January 1, 2018 and the adoption of ASU 2016-01 discussed in Note 2 to our consolidated financial statements elsewhere in this Report, the HBL securities were called “available-for-sale securities” and unrealized holding gains and losses, including changes in foreign currency exchange rates, were reported in other comprehensive income or loss, net of tax, and were a component of the accumulated other comprehensive income or loss on the consolidated balance sheets. Beginning on January 1, 2018, in accordance with our adoption of ASU 2016-01, all gains and losses we generate each period due to changes in fair market value, including changes in foreign currency exchange rates, from the HBL equity securities are included in other income and expenses, net, in our consolidated statements of operations.

For the year ended December 31, 2018, we recorded an unrealized gain of \$0.7 million due to the increase in fair market value of the HBL marketable equity securities from January 1, 2018 to December 31, 2018. For the year ended December 31, 2018, we recorded an unrealized gain of \$0.5 million due to the increase in fair market value of the AgeX marketable equity securities from November 28, 2018 to December 31, 2018.

*Loss on extinguishment of related party convertible debt* – We recognized a \$2.8 million noncash loss on extinguishment of related party convertible debt in connection with the purchase of all of the outstanding Cell Cure convertible notes from HBL on July 10, 2017.

*Other income and expenses, net* – Other income and expenses, net, in 2018 and 2017 consist primarily of net foreign currency transaction gains and losses recognized by Cell Cure and ESI, and changes in the fair value of the Cell Cure liability classified warrants. Foreign currency transaction gains and losses for the periods presented are principally related to the remeasurement of the US dollar denominated notes payable by Cell Cure to BioTime.

## **Income Taxes**

The deconsolidation of Asterias and OncoCyte financial statements from BioTime were not taxable transactions and did not create a current income tax payment obligation. The market values of the Asterias and OncoCyte shares we hold create a deferred tax liability to us based on the closing market prices of the shares, less our tax basis in the shares. The deferred tax liability generated by the Asterias and OncoCyte shares that we hold is a source of taxable income to us that will more likely than not result in the realization of our deferred tax assets to the extent of those deferred tax liabilities. Because the deferred tax liabilities are determined based on the closing prices of those shares and, due to the inherent unpredictability of future prices of those shares, we cannot reliably estimate or project those deferred tax liabilities on an annual basis. Therefore, the deferred tax liabilities pertaining to Asterias and OncoCyte shares, measured as of the period end being reported, and the related impact to the valuation allowance and deferred tax assets, are recorded in the period in which they occur. The income tax consequences of the AgeX Deconsolidation are discussed below.

On March 23, 2018, Ascendance was acquired by a third party in a merger through which AgeX received approximately \$3.2 million in cash for its shares of Ascendance common stock. For financial reporting purposes, AgeX recognized a \$3.2 million gain as a sale of its equity method investment in Ascendance. The sale was a taxable transaction to AgeX generating a taxable gain of approximately \$2.2 million. We have sufficient net operating losses to offset the entire gain resulting in no income taxes due.

The Juvenescence Transaction was a taxable event for us that resulted in a gross taxable gain of approximately \$29.4 million, which we expect to be fully offset with available net operating losses (“NOL”) carryforwards, resulting in no net income taxes due. Although the AgeX Deconsolidation on August 30, 2018 was not a taxable transaction to us and did not result in a current tax payment obligation, the financial reporting gain on the AgeX Deconsolidation generated a deferred tax liability, primarily representing the difference between book and tax basis of AgeX common stock on the AgeX Deconsolidation date. We expect this deferred tax liability to be fully offset by a corresponding release of our valuation allowance on deferred tax assets, resulting in no income tax provision or benefit from the AgeX Deconsolidation. The deferred tax liabilities on our investments in OncoCyte and Asterias, combined with the deferred tax liability generated by the fair value of our retained marketable securities in AgeX, are considered to be

sources of taxable income that will more likely than not result in the realization of its deferred tax assets to the extent of those deferred tax liabilities, thereby reducing the need for a valuation allowance.

The distribution of AgeX shares of common stock to BioTime shareholders on November 28, 2018 was a taxable event for us that resulted in a gross taxable gain of approximately \$26.4 million, which we expect to be fully offset with available net operating losses, resulting in no income taxes due.

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. For federal and state income tax purposes, as a result of the deconsolidation of AgeX, Asterias and OncoCyte and the deferred tax liabilities generated from the fair values of AgeX, Asterias and OncoCyte shares from the respective deconsolidation dates, including the changes to those deferred tax liabilities due to changes in the AgeX, Asterias and OncoCyte stock prices, our deferred tax assets exceeded our deferred tax liabilities as of December 31, 2018 and 2017. As a result, we established a full valuation allowance as of December 31, 2018 and 2017 due to the uncertainty of realizing future tax benefits from our net operating loss carryforwards and other deferred tax assets.

For the year ended December 31, 2018, because we experienced a loss from continuing operations but generated other comprehensive income attributable to foreign currency translation adjustments, we allocated income tax expense against the component of foreign currency translation adjustment in 2018 using a 21% tax rate. Income tax benefit related to continuing operations for the year ended December 31, 2018 includes a tax benefit of \$0.3 million due to the required intraperiod tax allocation. Conversely, other comprehensive income attributable to foreign currency translation adjustments for the year ended December 31, 2018 is net of an income tax expense of \$0.3 million. No income tax provision or benefit was recorded for the year ended December 31, 2017 due to a full valuation allowance on the deferred tax assets.

We expect that deferred income tax expense or benefit we record each reporting period, if any, will vary depending on the change in the closing stock prices of OncoCyte shares, including any changes in the fair value of our AgeX shares, from period to period and the related changes in those deferred tax liabilities and our deferred tax assets and other credits, including changes in the valuation allowance, for each period.

See Note 19 to our consolidated financial statements included elsewhere in this Report for the Asterias Merger that was completed on March 8, 2019. We are still evaluating whether the Asterias Merger is deemed to be a change of control, as defined by Internal Revenue Code Section 382, in which, if there is a change of control as of the merger date, utilization of the NOL and tax credit carryforwards may be subject to an annual limitation regarding their utilization against Asterias' taxable income in future periods.

### **Liquidity and Capital Resources**

At December 31, 2018, we had \$23.6 million of cash and cash equivalents on hand. We also hold OncoCyte shares valued at \$20.3 million as of December 31, 2018, that we may use for liquidity, as necessary and as market conditions allow. The market values shown may not represent the amount that could be realized in a sale of 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.

Since inception, we have incurred significant net losses and have funded our operations primarily through the issuance of equity securities, sale of common stock of a former subsidiary, receipt of research grants, royalties from product sales, license revenues and sales of research products. At December 31, 2018, we had an accumulated deficit of approximately \$261.9 million, working capital of \$29.5 million and shareholders' equity of \$92.2 million. We evaluated our projected cash flows and believe that our \$30.7 million of cash, cash equivalents and marketable equity securities at December 31, 2018, plus our \$20.3 million investment in OncoCyte and the \$2.1 million receivable from OncoCyte we collected on February 15, 2019, provide sufficient cash, cash equivalents, and liquidity 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.

On November 7, 2018, we entered into a definitive agreement to acquire via merger the remaining 61% ownership interest in Asterias Biotherapeutics, Inc. that we did not own. The merger was completed effective March 8, 2019 and as of that date, Asterias became our wholly-owned subsidiary and we will consolidate Asterias' operations and results with our operations and results beginning on that date. As we integrate Asterias' operations into our own, we expect to make extensive reductions in headcount and to reduce non-clinical related spend, in each case, as compared to Asterias' operations before the acquisition. See Note 19 to our consolidated financial statements included elsewhere in this Report.

Our projected cash flows are subject to various risks and uncertainties, and 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 projection of future costs, revenues, and rates of expenditure. For example, clinical trials being conducted for our OpRegen program will be funded in part with funds from grants and not from cash on hand. If we were to lose our grant funding or we are unable to continue to provide working capital to the OpRegen program, we may be required to delay, postpone, or cancel our clinical trials or limit the number of clinical trial sites, unless we are able to obtain adequate financing from another source that could be used for our clinical trials. In addition, we expect to incur significant costs in connection with the acquisition of Asterias and with integrating its operations. We may incur additional costs to maintain employee morale and to retain key employees. We will also incur significant fees and expenses relating to legal, accounting and other transaction fees and other costs associated with the merger. 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 and affiliates could result in the dilution of the interests of present shareholders.

#### *Cash used in operating activities*

During 2018, our total research and development expenses, including \$0.8 million in nonrecurring acquired in-process research and development expenses, were \$21.8 million and our general and administrative expenditures were \$24.7 million. Net loss attributable to BioTime for 2018 amounted to \$46.0 million. Net cash used in operating activities during 2018 was \$30.9 million. The difference between the net loss and net cash used in operating activities was primarily attributable to the following noncash items: \$78.5 million gain on sale of AgeX shares and the AgeX Deconsolidation; \$47.9 million unrealized loss on our equity method investment in OncoCyte at fair value; \$35.4 million unrealized loss on our equity method investment in Asterias at fair value; \$4.2 million unrealized loss on our equity method investment in AgeX at fair value; stock-based compensation expense of \$5.4 million; depreciation and amortization expense of \$3.3 million; a \$1.8 million foreign currency remeasurement and other loss; and a \$3.2 million gain on the disposition of AgeX's Ascendance common stock. Changes in working capital also provided \$0.6 million from operating activities.



*Cash used in investing activities*

During 2018, we generated \$11.8 million in net cash provided by investing activities due primarily to \$21.6 million in proceeds from the sale of our AgeX shares to Juvenescence and \$3.2 million in proceeds from the sale of equity method investment in Ascendance prior to the AgeX Deconsolidation. These amounts were partially offset by a \$9.7 million deconsolidation of AgeX's cash and cash equivalents as part of the AgeX Deconsolidation, \$1.9 million used to purchase certain intellectual property and in-process research and development by AgeX before the AgeX Deconsolidation and \$1.4 million to purchase property and equipment, including payments on construction in progress at our Cell Cure facility lease.

*Cash provided by financing activities*

During 2018, we generated \$5.8 million in net cash from financing activities, which was due primarily to \$5.0 million in proceeds from our sale of AgeX shares to Juvenescence and \$1.0 million in proceeds to AgeX from the sale of AgeX warrants to investors, both occurring prior to the AgeX Deconsolidation.

**Off-Balance Sheet Arrangements**

As of December 31, 2018, we did not have any off-balance sheet arrangements, as defined in Item 303(a) (4) (ii) of SEC Regulation S-K.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Under SEC rules and regulations, as a smaller reporting company, we are not required to provide the information required by this item.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**Index to consolidated financial statements**

<u>Report of OUM &amp; CO. LLP, Independent Registered Public Accounting Firm– Audit Opinion</u>	59
<u>Report of OUM &amp; CO. LLP, Independent Registered Public Accounting Firm – Internal Controls Opinion</u>	60
Financial Statements:	
<u>Consolidated Balance Sheets</u>	61
<u>Consolidated Statements of Operations</u>	62
<u>Consolidated Statements of Comprehensive Loss</u>	63
<u>Consolidated Statements of Changes in Shareholders Equity</u>	64
<u>Consolidated Statements of Cash Flows</u>	65

See accompanying notes to consolidated financial statements.

## **Report of Independent Registered Public Accounting Firm**

Shareholders and Board of Directors

BioTime, Inc.

Alameda, California

### **Opinion on the Consolidated Financial Statements**

We have audited the consolidated balance sheets of BioTime, Inc. and Subsidiaries (collectively, the “Company”) as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, changes in shareholders’ equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated March 14, 2019 expressed an unqualified opinion thereon.

### **Change in Accounting Principle**

As discussed in Note 2 to the accompanying financial statements, the Company has changed their method of accounting for revenue in 2018 due to the adoption of Financial Accounting Standards Board (United States) Accounting Standard Codification Topic No. 606, *Revenue from Contracts with Customers*.

### **Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

*/s/ OUM & CO. LLP*

San Francisco, California

March 14, 2019

We have served as the Company's auditor since 2014.

## Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors

BioTime, Inc.

Alameda, California

## Opinion on Internal Control over Financial Reporting

We have audited BioTime, Inc. and Subsidiaries' (the "Company's") internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes and our report dated March 14, 2019 expressed an unqualified opinion thereon.

## Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, *Management's Report on Internal Control over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an

understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### **Definition and Limitations of Internal Control over Financial Reporting**

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

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

*/s/ OUM & CO. LLP*

San Francisco, California

March 14, 2019

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

	<b>December 31, 2018</b>	<b>December 31, 2017</b>
	<b>(Notes 1 and 4)</b>	<b>(Notes 1 and 4)</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$23,587	\$36,838
Marketable equity securities	7,154	1,337
Trade accounts and grants receivable, net	767	780
Landlord receivable	840	-
Receivables from affiliates, net	2,112	2,266
Prepaid expenses and other current assets	1,898	1,402
Total current assets	36,358	42,623
<b>NONCURRENT ASSETS</b>		
Property and equipment, net	5,835	5,533
Deposits and other long-term assets	505	1,018
Promissory note from Juvenescence (Note 3)	22,104	-
Equity method investment in OncoCyte, at fair value (Note 6)	20,250	68,235
Equity method investment in Asterias, at fair value (Notes 7 and 19)	13,483	48,932
Intangible assets, net	3,125	6,900
<b>TOTAL ASSETS</b>	<b>\$101,660</b>	<b>\$173,241</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued liabilities	\$6,463	\$5,718
Capital lease and lease liability, current portion	237	212
Promissory notes, current portion	70	152
Deferred license and subscription revenues	-	488
Deferred grant revenue	42	309
Total current liabilities	6,812	6,879
<b>LONG-TERM LIABILITIES</b>		
Deferred rent liabilities, net of current portion	244	105
Lease liability, net of current portion	1,854	1,019
Capital lease, net of current portion	104	132
Promissory notes, net of current portion	-	18
Liability classified warrants and other long-term liabilities	400	825

TOTAL LIABILITIES	9,414	8,978
Commitments and contingencies (Note 15)		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of December 31, 2018 and 2017, respectively	-	-
Common stock, no par value, authorized 250,000 shares; 127,136 and 126,866 shares issued and outstanding as of December 31, 2018 and 2017, respectively	354,270	378,487
Accumulated other comprehensive income	1,426	451
Accumulated deficit	(261,856)	(216,297)
BioTime, Inc. shareholders' equity	93,840	162,641
Noncontrolling interest (deficit)	(1,594)	1,622
Total shareholders' equity	92,246	164,263
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 101,660	\$ 173,241

See accompanying notes to the consolidated financial statements.



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

	Year Ended December 31,	
	2018	2017
<b>REVENUES:</b>		
Grant revenue	\$3,572	\$1,666
Royalties from product sales and license fees	392	389
Subscription and advertisement revenues	691	1,395
Sale of research products and services	333	8
Total revenues	4,988	3,458
Cost of sales	(302)	(168)
Gross profit	4,686	3,290
<b>OPERATING EXPENSES:</b>		
Research and development	(20,955)	(24,024)
Acquired in-process research and development	(800)	-
General and administrative	(24,726)	(19,922)
Total operating expenses	(46,481)	(43,946)
Gain on sale of assets	-	1,754
Loss from operations	(41,795)	(38,902)
<b>OTHER INCOME/(EXPENSES):</b>		
Interest income (expense), net	711	(692)
Gain on sale of equity method investment in Ascendance	3,215	-
Gain on sale of AgeX shares and deconsolidation of AgeX	78,511	-
Gain on deconsolidation of OncoCyte (Note 5)	-	71,697
Loss on equity method investment in OncoCyte at fair value (Note 6)	(47,985)	(2,935)
Loss on equity method investment in Asterias at fair value (Note 7)	(35,449)	(51,107)
Loss on equity method investment in AgeX at fair value (Note 2)	(4,181)	-
Unrealized gain on marketable equity securities (Note 2)	1,158	-
Loss on extinguishment of related party convertible debt	-	(2,799)
Other income/(expense), net	(1,315)	1,449
Total other income (expenses), net	(5,335)	15,613
<b>LOSS BEFORE INCOME TAXES</b>	<b>(47,130)</b>	<b>(23,289)</b>
Income tax benefit	346	-
<b>NET LOSS</b>	<b>(46,784)</b>	<b>(23,289)</b>
Net loss attributable to noncontrolling interest	794	3,313

NET LOSS ATTRIBUTABLE TO BIOTIME, INC.	\$(45,990)	\$(19,976)
NET LOSS PER COMMON SHARE: BASIC AND DILUTED	\$(0.36)	\$(0.17)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: BASIC AND DILUTED	126,903	114,476

See accompanying notes to the consolidated financial statements.

**BIOTIME, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS****(IN THOUSANDS)**

	Year Ended December 31,	
	2018	2017
NET LOSS	\$(46,784)	\$(23,289)
Other comprehensive income, net of tax:		
Foreign currency translation adjustments, net of tax	1,303	668
Available-for-sale investments:		
Unrealized gain on available-for-sale securities, net of taxes	-	521
COMPREHENSIVE LOSS	(45,481)	(22,100)
Less: comprehensive loss attributable to noncontrolling interest	794	3,313
COMPREHENSIVE LOSS ATTRIBUTABLE TO BIOTIME, INC. COMMON SHAREHOLDERS	\$(44,687)	\$(18,787)

See accompanying notes to the consolidated financial statements.

## BIOTIME, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

(IN THOUSANDS)

	Preferred Shares	Common Shares Number	Amount	Treasury Shares Number	Amount	Accumulated Deficit	Noncontrolling Interest	Accumulated Other Comprehensive Income/(Loss)	Total Shareholders' Equity	
BALANCE AT DECEMBER 31, 2016	-	\$ -	103,396	\$ 317,878	(620)	\$ (2,891)	\$ (196,321)	\$ 12,580	\$ (738)	\$ 130,508
Sale of common shares, net of financing fees	-	-	18,511	45,068	-	-	-	-	-	45,068
Sale of common shares at the market, net of fees	-	-	300	835	-	-	-	-	-	835
Purchase of shares from a related party and retired Shares issued upon vesting of restricted stock units, net of shares retired to pay employee's taxes	-	-	(300)	(843)	-	-	-	-	-	(843)
Common shares issued for consulting services in lieu of cash	-	-	1	3	-	-	-	-	-	3
Stock-based compensation	-	-	-	3,019	-	-	-	-	-	3,019
Stock-based compensation in subsidiaries	-	-	-	-	-	-	-	913	-	913
Exercise of options	-	-	9	25	-	-	-	-	-	25
Exercise of subsidiary options	-	-	-	-	-	-	-	4	-	4
Deconsolidation of OncoCyte	-	-	-	(3,253)	620	2,891	-	(8,512)	-	(8,874)

Edgar Filing: BIOTIME INC - Form 10-K

Sale of subsidiary shares in AgeX	-	-	-	100	-	-	-	9,868	-	9,968
Subsidiary financing transactions with noncontrolling interests – AgeX Beneficial	-	-	-	8,207	-	-	-	(8,207)	-	-
conversion feature on convertible debt issued to Cell Cure’s noncontrolling interests	-	-	-	-	-	-	-	304	-	304
Foreign currency translation adjustment	-	-	-	-	-	-	-	-	668	668
Unrealized gain on available-for-sale securities	-	-	-	-	-	-	-	-	521	521
Subsidiary financing and other transactions with noncontrolling interests –LifeMap Sciences, LifeMap Solutions, OrthoCyte, and ReCyte, net	-	-	-	5,495	-	-	-	(5,495)	-	-
Common shares issued to purchase Cell Cure ordinary shares and Cell Cure Notes from noncontrolling interests in Cell Cure	-	-	4,925	15,217	-	-	-	-	-	15,217
Purchase of noncontrolling interests in Cell Cure	-	-	-	(10,117)	-	-	-	3,480	-	(6,637)
Purchase of beneficial conversion option at intrinsic value in Cell Cure Notes	-	-	-	(3,101)	-	-	-	-	-	(3,101)
NET LOSS	-	-	-	-	-	-	(19,976)	(3,313)	-	(23,289)
BALANCE AT DECEMBER 31, 2017	-	\$ -	126,866	\$378,487	-	\$-	\$(216,297)	\$ 1,622	\$ 451	\$ 164,263

Cumulative-effect adjustment for adoption of ASU 2016-01 on January 1, 2018	-	-	-	-	-	-	328	-	(328)	-
Cumulative-effect adjustment for adoption of Accounting Standard Codification, Topic 606, on January 1, 2018	-	-	-	-	-	-	103	-	-	103
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	270	(203)	-	-	-	-	-	(203)
Stock-based compensation	-	-	-	4,912	-	-	-	-	-	4,912
Stock-based compensation in subsidiaries	-	-	-	-	-	-	-	490	-	490
Sale of subsidiary shares in AgeX	-	-	-	-	-	-	-	5,239	-	5,239
Sale of subsidiary warrants in AgeX	-	-	-	-	-	-	-	1,000	-	1,000
Deconsolidation of AgeX	-	-	-	(163)	-	-	-	(3,467)	-	(3,630)
Distribution of AgeX shares to BioTime shareholders, on a pro rata basis, at fair value as a dividend-in-kind	-	-	-	(34,409)	-	-	-	-	-	(34,409)
Subsidiary financing transactions with noncontrolling interests – AgeX	-	-	-	3,790	-	-	-	(3,790)	-	-
Foreign currency translation adjustments	-	-	-	-	-	-	-	-	1,303	1,303
Subsidiary financing and other transactions with noncontrolling interests – Cell Cure	-	-	-	1,894	-	-	-	(1,894)	-	-

Edgar Filing: BIOTIME INC - Form 10-K

Purchase of noncontrolling interests in Cell Cure	-	-	-	(38)	-	-	-	-	-	(38)
NET LOSS	-	-	-	-	-	-	(45,990)	(794)	-	(46,784)
BALANCE AT DECEMBER 31, 2018	-	\$ -	127,136	\$354,270	-	\$-	\$(261,856)	\$(1,594)	\$ 1,426	\$92,246

See accompanying notes to the consolidated financial statements.

**BIOTIME, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****(IN THOUSANDS)**

	Year Ended December 31,	
	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss attributable to BioTime, Inc.	\$(45,990)	\$(19,976)
Net loss attributable to noncontrolling interest	(794)	(3,313)
Adjustments to reconcile net loss attributable to BioTime, Inc. to net cash used in operating activities:		
Gain on sale of AgeX shares and deconsolidation of AgeX	(78,511)	-
Gain on deconsolidation of OncoCyt	-	(71,697)
Gain on sale of equity method investment in Ascendance	(3,215)	-
Acquired in-process research and development	800	-
Unrealized loss on equity method investment in OncoCyt at fair value	47,985	2,935
Unrealized loss on equity method investment in Asterias at fair value	35,449	51,107
Unrealized loss on equity method investment in AgeX at fair value	4,181	-
Unrealized gain on marketable equity securities	(1,158)	-
Income tax benefit	(346)	-
Depreciation expense, including amortization of leasehold improvements	1,081	947
Amortization of intangible assets	2,192	2,349
Stock-based compensation	5,402	3,932
Liability classified warrants	(384)	797
Amortization of discount on related party convertible debt	-	640
Foreign currency remeasurement and other (gain) loss	1,788	(1,761)
Gain on sale of assets	-	(1,754)
Loss on extinguishment of related party debt	-	2,799
Changes in operating assets and liabilities:		
Accounts and grants receivable, net	46	(172)
Due from affiliates	559	1,157
Prepaid expenses and other current assets	(437)	145
Other long-term assets and liabilities	(487)	(22)
Accounts payable and accrued liabilities	1,100	1,299
Deferred revenues and grant income	(287)	243
Deferred grant expense	-	(227)
Deferred rent liabilities	144	55
Net cash used in operating activities	(30,882)	(30,517)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Deconsolidation of cash and cash equivalents of AgeX	(9,704)	-
Deconsolidation of cash and cash equivalents of OncoCyt	-	(8,898)
Proceeds from the sale of AgeX common stock to Juvenescence	21,600	-



Edgar Filing: BIOTIME INC - Form 10-K

Proceeds from the sale of equity method investment in Ascendance	3,215	-
Purchase of in-process research and development by AgeX	(1,872)	-
Purchase of property and equipment	(556)	(1,326)
Payments on construction in progress	(859)	-
Purchase of foreign available-for-sale securities	-	(189)
Proceeds from sale of assets	-	200
Security deposit paid and other	(8)	(12)
Net cash provided by (used in) investing activities	11,816	(10,225)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common shares	-	48,875
Fees paid on sale of common shares	-	(3,798)
Proceeds from exercise of stock options	-	25
Common shares received and retired for employee taxes paid	(203)	(45)
Proceeds from exercise of subsidiary stock options and warrants	-	4
Proceeds from sale of subsidiary common shares and warrants	6,000	9,968
Proceeds from sale of common shares at-the-market, net of fees	-	835
Purchase and retirement of common shares from a related party	-	(843)
Repayment of lease liability and capital lease obligation	(248)	(204)
Reimbursement from landlord on construction in progress	364	198
Proceeds from issuance of related party convertible debt	-	425
Repayment of promissory notes	(101)	(49)
Payment to repurchase subsidiary shares	(38)	-
Net cash provided by financing activities	5,774	55,391
Effect of exchange rate changes on cash, cash equivalents and restricted cash	6	101
<b>NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>	<b>(13,286)</b>	<b>14,750</b>
At beginning of year	37,685	22,935
At end of year	\$24,399	\$37,685
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>		
Cash paid during year for interest	\$155	\$156
<b>SUPPLEMENTAL SCHEDULE OF NONCASH FINANCING AND INVESTING ACTIVITIES:</b>		
Sale of AgeX common stock in exchange for a promissory note from Juvenescence	\$21,600	\$-
Distribution of AgeX common stock to BioTime shareholders, on a pro rata basis, as a dividend-in-kind, at fair value	34,409	-
BioTime common stock issued to purchase Cell Cure ordinary shares and Convertible Notes from noncontrolling interests in Cell Cure	-	15,217
Extinguishment of related party convertible debt, including accrued interest, with BioTime common stock	-	2,680
Capital expenditure funded by capital lease liability	-	151
Landlord receivable and lease liability	840	-
Construction in progress in accounts payable and accrued expenses	455	-

See accompanying notes to the consolidated financial statements.



**BIOTIME, INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization, Basis of Presentation and Liquidity**

*General* – BioTime is a clinical-stage biotechnology company developing new cellular therapies for degenerative retinal diseases, neurological conditions associated with demyelination, and aiding the body in detecting and combating cancer. BioTime’s programs are based on its proprietary cell-based therapy platform and associated development and manufacturing capabilities. With this platform BioTime develops and manufactures specialized, terminally-differentiated human cells from our pluripotent and progenitor cell starting materials. These differentiated cells are developed either to replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury, or administered as a means of helping the body mount an effective immune response to cancer.

BioTime has three cell therapy programs in clinical development:

*OpRegen*<sup>®</sup>, a retinal pigment epithelium cell replacement therapy currently in a Phase I/IIa multicenter clinical trial for the treatment of advanced dry-age-related macular degeneration (“dry-AMD”) with geographic atrophy. There currently are no therapies approved by the U.S. Food and Drug Administration (“FDA”) for dry-AMD, which accounts for approximately 85-90% of all AMD cases and is the leading cause of blindness in people over the age of 60.

*OPCI*, an oligodendrocyte progenitor cell therapy currently in a Phase I/IIa multicenter clinical trial for acute spinal cord injuries (“SCI”). This clinical trial has been partially funded by the California Institute for Regenerative Medicine (“CIRM”).

*VAC2*, an allogeneic (non-patient-specific or “off-the-shelf”) cancer immunotherapy of antigen-presenting dendritic cells currently in a Phase I clinical trial in non-small cell lung cancer. This clinical trial is being funded and conducted by Cancer Research UK (“CRUK”), the world’s largest independent cancer research charity.

BioTime also has cell/drug delivery programs that are based upon its proprietary *HyStem*<sup>®</sup> cell and drug delivery matrix technology. *HyStem*<sup>®</sup> was designed to support the formulation, transfer, retention, and engraftment of cellular therapies.

BioTime is also enabling early-stage programs in other new technologies through its own research programs as well as through other subsidiaries, affiliates or investees.

*AgeX Therapeutics, Inc. Deconsolidation and Distribution* - In 2017, BioTime formed AgeX Therapeutics, Inc. (“AgeX”) to continue development of certain early-stage programs relating to cell immortality, regenerative biology, aging, and age-related diseases. AgeX’s initial programs focus on utilizing brown adipose tissue to target diabetes, obesity, and heart disease; and induced tissue regeneration technology utilizing the human body’s own abilities to scarlessly regenerate tissues damaged from age or trauma.

On August 17, 2017, AgeX completed an asset acquisition and stock sale pursuant to which it received certain assets from BioTime for use in its research and development programs and raised \$10.0 million in cash from investors to finance its operations.

As discussed in Note 3, on August 30, 2018, BioTime entered into a Stock Purchase Agreement with Juvenescence Limited (“Juvenescence”) and AgeX pursuant to which BioTime sold 14,400,000 shares of its shares of AgeX common stock to Juvenescence for \$3.00 per share (the “Juvenescence Transaction”). Prior to the Juvenescence Transaction, Juvenescence owned 5.6% of AgeX’s issued and outstanding common stock. Upon completion of the Juvenescence Transaction, BioTime’s ownership in AgeX decreased from 80.4% to 40.2% of AgeX’s issued and outstanding shares of common stock, and Juvenescence’s ownership in AgeX increased from 5.6% to 45.8% of AgeX’s issued and outstanding shares of common stock. As a result of the Juvenescence Transaction, as of August 30, 2018, BioTime owned less than 50% of AgeX’s outstanding common stock and experienced a loss of control of AgeX in accordance with accounting principles generally accepted in the United States (“GAAP”). Under GAAP, loss of control of a subsidiary is deemed to have occurred when, among other things, a parent company owns less than a majority of the outstanding common stock of the subsidiary, lacks a controlling financial interest in the subsidiary, and is unable to unilaterally control the subsidiary through other means such as having the ability or being able to obtain the ability to elect a majority of the subsidiary’s Board of Directors. BioTime determined that all of these loss of control factors were present with respect to AgeX on August 30, 2018. Accordingly, BioTime has deconsolidated AgeX’s consolidated financial statements and consolidated results of operations from BioTime, effective August 30, 2018 (the “AgeX Deconsolidation”), in accordance with Accounting Standards Codification, or ASC 810-10-40-4(c), *Consolidation*. Beginning on August 30, 2018 through November 28, 2018, BioTime accounted for the AgeX common stock it holds using the equity method of accounting at fair value (see Note 4).

On November 28, 2018, BioTime distributed 12.7 million shares of AgeX common stock owned by BioTime to holders of BioTime common shares, on a pro rata basis, in the ratio of one share of AgeX common stock for every 10 BioTime common shares owned (the “AgeX Distribution”) (see Note 4). Immediately following the distribution, BioTime owned 1.7 million shares of AgeX common stock, all of which it still owns, and which represents approximately 4.8% of AgeX’s outstanding common stock as of December 31, 2018 and which shares BioTime holds as marketable equity securities.

BioTime also has significant equity holdings in two publicly traded companies, OncoCyte Corporation (“OncoCyte”) and Asterias Biotherapeutics, Inc. (“Asterias”), which BioTime founded and, until recently, were majority-owned and consolidated subsidiaries. OncoCyte (NYSE American: OCX) is developing confirmatory diagnostic tests for lung cancer utilizing novel liquid biopsy technology. Asterias (NYSE American: AST) is presently focused on advancing three clinical-stage programs that have the potential to address areas of very high unmet medical needs in the fields of neurology (spinal cord injury) and oncology (Acute Myeloid Leukemia and lung cancer). See Note 19 for the definitive merger agreement entered into by BioTime and Asterias on November 7, 2018, for BioTime to acquire the remaining ownership interest in Asterias, which was completed on March 8, 2019 (the “Asterias Merger”).

Beginning on February 17, 2017, BioTime deconsolidated OncoCyte’s financial statements and results of operations from BioTime (the “OncoCyte Deconsolidation”) (see Notes 5 and 6).

Beginning on May 13, 2016, BioTime deconsolidated Asterias’ financial statements and results of operations from BioTime (the “Asterias Deconsolidation”) (see Notes 5 and 7).

*Use of estimates* - The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period with consideration given to materiality. Significant estimates and assumptions which are subject to significant judgment include those related to going concern assessment of consolidated financial statements, useful lives associated with long-lived assets, including evaluation of asset impairment, allowances for uncollectible accounts receivables, 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.

*Principles of consolidation* – BioTime’s consolidated financial statements include the accounts of its subsidiaries. The following table reflects BioTime’s ownership, directly or through one or more subsidiaries, of the outstanding shares of its operating subsidiaries as of December 31, 2018.

<b>Subsidiary</b>	<b>Field of Business</b>	<b>BioTime Ownership</b>	<b>Country</b>
Cell Cure Neurosciences Ltd. ("Cell Cure")	Products to treat age-related macular degeneration	99% <sup>(1)</sup>	Israel
ES Cell International Pte. Ltd. ("ESI")	Stem cell products for research, including clinical grade cell lines produced under cGMP	100%	Singapore
OrthoCyte Corporation ("OrthoCyte")	Developing bone grafting products for orthopedic diseases and injuries	99.8%	USA

(1) Includes shares owned by BioTime and ESI

All material intercompany accounts and transactions have been eliminated in consolidation. As of December 31, 2018, BioTime consolidated its direct and indirect wholly-owned or majority-owned subsidiaries because BioTime has the ability to control their operating and financial decisions and policies through its ownership, and the noncontrolling interest is reflected as a separate element of shareholders' equity on BioTime's consolidated balance sheets.

*Liquidity* – Since inception, BioTime has incurred significant operating losses and has funded its operations primarily through the issuance of equity securities, sale of common stock of a former subsidiary, receipt of research grants, royalties from product sales, license revenues and sales of research products. At December 31, 2018, BioTime had an accumulated deficit of approximately \$261.9 million, working capital of \$29.5 million and shareholders' equity of \$92.2 million. BioTime has evaluated its projected cash flows and believes that its \$30.7 million of cash, cash equivalents and marketable equity securities at December 31, 2018, plus the \$2.1 million receivable from OncoCyte collected on February 15, 2019, provide sufficient cash, cash equivalents, and liquidity to carry out BioTime's current operations through at least twelve months from the issuance date of the consolidated financial statements included herein. BioTime also holds shares of OncoCyte common stock with a value of \$20.3 million at December 31, 2018. Although BioTime has no present plans to liquidate its holdings of OncoCyte shares, if BioTime needs near term working capital or liquidity to supplement its cash and cash equivalents for its operations, BioTime may sell some, or all, of its OncoCyte shares, as necessary.

The AgeX Distribution was completed on November 28, 2018 and AgeX became a public company. BioTime will continue to hold a minor interest in AgeX common stock that may be a source of additional liquidity to BioTime as a marketable equity security.

If the Juvenescence Promissory Note discussed in Note 3 is converted to Juvenescence common stock prior to its maturity date, the Juvenescence common stock may be a marketable security that BioTime may use to supplement its liquidity, as needed. If the Promissory Note is not converted, it is payable in cash, plus accrued interest, at maturity. There can be no assurance that the Promissory Note will be converted prior to maturity.

On November 7, 2018, BioTime entered into a definitive agreement to acquire via merger the remaining 61% ownership interest in Asterias that it did not own. The merger was completed effective March 8, 2019 and as of that date, Asterias became BioTime's wholly-owned subsidiary and BioTime will consolidate Asterias' operations and results with its operations and results beginning on that date (see Note 19). As we integrate Asterias' operations into our own, we expect to make extensive reductions in headcount and to reduce non-clinical related spend, in each case, as compared to Asterias' operations before the acquisition.

BioTime's projected cash flows are subject to various risks and uncertainties, and the unavailability or inadequacy of financing to meet future capital needs could force BioTime to modify, curtail, delay, or suspend some or all aspects of its planned operations. BioTime's determination as to when it will seek new financing and the amount of financing that it will need will be based on BioTime's evaluation of the progress it makes in its research and development programs, any changes to the scope and focus of those programs, and projection of future costs, revenues, and rates of expenditure. For example, clinical trials being conducted for our *OpRegen*<sup>®</sup> program will be funded in part with funds from grants and not from cash on hand. If BioTime were to lose grant funding or is unable to continue to provide working capital to the OpRegen program, BioTime may be required to delay, postpone, or cancel clinical trials or limit the number of clinical trial sites, unless it is able to obtain adequate financing from another source that could be used for clinical trials. In addition, BioTime expects to incur significant costs in connection with the acquisition of Asterias and with integrating its operations. BioTime may incur additional costs to maintain employee morale and to retain key employees. BioTime will also incur significant fees and expenses relating to legal, accounting and other transaction fees and other costs associated with the merger. BioTime cannot assure that adequate financing will be available on favorable terms, if at all. Sales of additional equity securities by BioTime or its subsidiaries and affiliates could result in the dilution of the interests of present shareholders.

## **2. Summary of Significant Accounting Policies**

*Going concern assessment* – BioTime assesses going concern uncertainty for its consolidated financial statements to determine if BioTime has sufficient cash and cash equivalents on hand and working capital to operate for a period of at least one year from the date the consolidated financial statements are issued or are available to be issued, which is referred to as the “look-forward period” as defined by FASB's ASU No. 2014-15. As part of this assessment, based on

conditions that are known and reasonably knowable to BioTime, BioTime will consider various scenarios, forecasts, projections, and estimates, and BioTime will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail those expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, BioTime makes certain assumptions concerning its ability to curtail or delay research and development programs and expenditures within the look-forward period in accordance with ASU No. 2014-15.

*Cash and cash equivalents* – BioTime considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2018 and 2017, BioTime had \$20.4 million and \$32.1 million in money market funds, respectively, considered to be cash equivalents.

*Restricted cash* – BioTime has a certificate of deposit in the amount of \$812,000 as required under the Alameda Lease and the Cell Cure Lease discussed in Note 15, as BioTime is restricted from using the cash for working capital purposes. Of this amount, \$346,000 is included in prepaids and other current assets and \$466,000 is included in deposits and other long-term assets as of December 31, 2018. On January 24, 2019, the landlord for the Alameda Lease reduced the security deposit to \$78,000 pursuant to the Alameda Lease agreement and released the \$346,000 to BioTime for general working capital purposes.

*Trade accounts and grants receivable, net* – Net trade receivables amounted to \$51,000 and \$139,000 and grants receivable amounted to \$716,000 and \$641,000 as of December 31, 2018 and 2017, respectively. Net trade receivables include allowance for doubtful accounts of approximately \$100,000 and \$422,000 as of December 31, 2018 and 2017, respectively, for those amounts deemed uncollectible by BioTime. BioTime establishes an allowance for doubtful accounts based on the evaluation of the collectability of its receivables on a variety of factors, including the length of time receivables are past due, significant events that may impair the customer's ability to pay, such as a bankruptcy filing or deterioration in the customer's operating results or financial position, and historical experience. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted.



*Financing receivable from Juvenescence* – BioTime accounts for the Promissory Note from Juvenescence as a financing receivable under ASC 310-10, *Receivables*, since it both represents a contractual right to receive cash on a fixed date at maturity and is recognized as an asset on BioTime’s consolidated balance sheet. Under ASC 310-10, the Promissory Note was issued at fair value on the Juvenescence Transaction date and subsequently carried at amortized cost with accrued interest, subject to impairment testing under ASC 310. Interest is accrued monthly under the provisions of the Promissory Note and all accrued interest, along with the principal of the Promissory Note, is payable at maturity two years after the closing of the Juvenescence Transaction, unless converted prior to that date (see Note 3). BioTime establishes an allowance for doubtful accounts based on the evaluation of the collectability of the Promissory Note and accrued interest on a variety of factors, as applicable, including significant events that may impair Juvenescence’s ability to pay, such as a bankruptcy filing or deterioration in Juvenescence’s operating results or financial position, the length of time receivable is past due and historical experience.

*Concentrations of credit risk* – Financial instruments that potentially subject BioTime to significant concentrations of credit risk consist primarily of cash and cash equivalents. BioTime limits the amount of credit exposure of cash balances by maintaining its accounts in high credit quality financial institutions. Cash equivalent deposits with financial institutions may occasionally exceed the limits of insurance on bank deposits; however, BioTime has not experienced any losses on such accounts.

*Fair Value Measurements* – Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value (ASC 820-10-50), *Fair Value Measurements and Disclosures*:

Level 1 – Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 – Inputs to the valuation methodology include quoted prices for similar assets or liabilities in active markets, and inputs that are observable for the assets or liability, either directly or indirectly, for substantially the full term of the financial instruments.

Level 3 – Inputs to the valuation methodology are unobservable; that reflect management’s own assumptions about the assumptions market participants would make and significant to the fair value.

In determining fair value, BioTime utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, and also considers counterparty credit risk in its assessment of fair value. For the periods presented, BioTime has no financial assets or liabilities recorded at fair value on a recurring basis, except for cash and cash equivalents consisting of money market funds, shares BioTime holds in Asterias and OncoCyte, and the marketable equity securities in AgeX and Hadasit Bio-Holdings Ltd. (“HBL”), which are carried at fair value based on the applicable period-end quoted market prices as a Level 1 input. BioTime also has certain liability classified warrants issued by Cell Cure which are carried at fair value based on Level 3 inputs (see Note 12).

The fair value of BioTime's assets and liabilities, which qualify as financial instruments under FASB guidance regarding disclosures about fair value of financial instruments, approximate the carrying amounts presented in the accompanying consolidated balance sheets. The carrying amounts of accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate fair values because of the short-term nature of these items.

*Equity method investments at fair value* – BioTime uses the equity method of accounting when it has the ability to exercise significant influence, but not control, as determined in accordance with GAAP, over the operating and financial policies of a company. For equity method investments which BioTime has elected to measure at fair value, unrealized gains and losses are reported in the consolidated statements of operations in other income and expenses, net.

As further discussed in Notes 6 and 7, BioTime has elected to account for its OncoCyte and Asterias shares at fair value using the equity method of accounting because beginning on February 17, 2017 and May 13, 2016, the respective dates on which BioTime deconsolidated OncoCyte and Asterias, BioTime has not had control of OncoCyte and Asterias, as defined by GAAP, but continues to exercise significant influence over those companies. Under the fair value method, BioTime's value in shares of common stock it holds in OncoCyte and Asterias is marked to market at each balance sheet date using the closing prices of OncoCyte and Asterias common stock on the NYSE American multiplied by the number of shares of OncoCyte and Asterias held by BioTime, with changes in the fair value of the OncoCyte and Asterias shares included in other income and expenses, net, in the consolidated statements of operations. The OncoCyte and Asterias shares are considered level 1 assets as defined by ASC 820, *Fair Value Measurements and Disclosures*.

On August 30, 2018, BioTime consummated the sale of AgeX Shares to Juvenescence (see Note 3). Prior to the Juvenescence Transaction, Juvenescence owned 5.6% of AgeX's issued and outstanding common stock. Upon completion of the Juvenescence Transaction, BioTime's ownership in AgeX decreased from 80.4% to 40.2% of AgeX's issued and outstanding shares of common stock, and Juvenescence's ownership in AgeX increased from 5.6% to 45.8% of AgeX's issued and outstanding shares of common stock. Accordingly, beginning on August 30, 2018, BioTime deconsolidated the financial statements and results of AgeX (see Note 4).

On November 28, 2018, BioTime completed the AgeX Distribution whereby following the AgeX Distribution, BioTime retained 1.7 million shares of AgeX common stock as a marketable equity security discussed below, which represents approximately 4.8% of AgeX's issued and outstanding shares of common stock (see Note 4).

Beginning on August 30, 2018 through November 28, 2018, the completion of the AgeX Distribution, BioTime held 40.2% of AgeX's issued and outstanding shares of common stock and therefore accounted for the AgeX shares in a manner similar to the accounting for Asterias and OncoCyte shares held discussed above, using the equity method of accounting at fair value. For the period from August 30, 2018, through November 28, 2018, BioTime recorded an unrealized loss of \$4.2 million due to the decrease in the AgeX stock price from August 30, 2018 to the AgeX Distribution date of November 28, 2018.

*Marketable equity securities* – BioTime accounts for the shares it holds in foreign equity securities in HBL and the AgeX shares of common stock it holds beginning on November 28, 2018, as marketable equity in accordance with ASC 320-10-25, *Investments – Debt and Equity Securities*, as amended by Accounting Standards Update (“ASU”) 2016-01, *Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, further discussed below.

The HBL shares have a readily determinable fair value quoted on the Tel Aviv Stock Exchange (“TASE”) (under trading symbol “HDST”) where share prices are denominated in New Israeli Shekels (NIS). The AgeX shares have a readily determinable fair value quoted on the NYSE American under trading symbol “AGE”. Accordingly, the marketable equity securities are considered level 1 assets as defined by ASC 820. These securities are held principally to meet future working capital needs. These securities are measured at fair value and reported as current assets on the consolidated balance sheets based on the closing trading price of the security as of the date being presented.

Beginning on January 1, 2018, with the adoption of ASU 2016-01 discussed below, the HBL securities are now called “marketable equity securities” and unrealized holding gains and losses on these securities, including changes in foreign currency exchange rates, are reported in the consolidated statements of operations in other income and expenses, net. Prior to January 1, 2018 and the adoption of ASU 2016-01, the HBL securities were called “available-for-sale securities” and unrealized holding gains and losses, including changes in foreign currency exchange rates, were reported in other comprehensive income or loss, net of tax, and were a component of the accumulated other comprehensive income or loss on the consolidated balance sheet. Realized gains and losses, and declines in value

judged to be other-than-temporary related to marketable equity securities, are included in other income and expenses, net, in the consolidated statements of operations.

On January 1, 2018, in accordance with the adoption of ASU 2016-01, BioTime recorded a cumulative-effect adjustment for the HBL available-for-sale-securities to reclassify the unrealized gain of \$328,000 included in consolidated accumulated other comprehensive income to the consolidated accumulated deficit balance.

For the year ended December 31, 2018, BioTime recorded an unrealized gain of \$677,000, included in other income and expenses, net, due to the increase in fair market value of the HBL marketable equity securities from January 1, 2018 to December 31, 2018. For the year ended December 31, 2018, BioTime recorded an unrealized gain of \$481,000, included in other income and expenses, net, due to the increase in fair market value of the AgeX marketable equity securities from November 28, 2018 to December 31, 2018.

*Property and equipment, net and construction in progress* – Property and equipment is stated at cost and is being depreciated using the straight-line method over their estimated useful lives ranging from 3 to 10 years. Leasehold improvements are amortized over the shorter of the useful life or the lease term. Construction in progress is not depreciated until the underlying asset is placed into service (see Note 15).

*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* – 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, BioTime evaluates 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.

*Accounting for warrants* – BioTime determines the accounting classification of warrants that it or its subsidiaries issue, as either liability or equity, by first assessing whether the warrants meet liability classification 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 considered liability classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or warrants that must or may require settlement by issuing variable number of shares. If warrants do not meet liability classification under ASC 480-10, BioTime assesses 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, BioTime assesses whether the warrants are indexed to its common stock or its 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, BioTime concludes 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 issuance date with no changes in fair value recognized subsequent to the issuance date. In 2017, Cell Cure issued certain liability classified warrants (see Note 12).

*Transactions with noncontrolling interests of subsidiaries* – BioTime accounts for a change in ownership interests in its subsidiaries that does not result in a change of control of the subsidiary by BioTime under the provisions of ASC 810-10-45-23, *Consolidation – Other Presentation Matters*, which prescribes the accounting for changes in ownership interest that do not result in a change in control of the subsidiary, as defined by GAAP, before and after the transaction. Under this guidance, changes in a controlling shareholder's ownership interest that do not result in a change of control, as defined by GAAP, in the subsidiary are accounted for as equity transactions. Thus, if the controlling shareholder retains control, no gain or loss is recognized in the statements of operations of the controlling shareholder. Similarly, the controlling shareholder will not record any additional acquisition adjustments to reflect its subsequent purchases of additional shares in the subsidiary if there is no change of control. Only a proportional and immediate transfer of carrying value between the controlling and the noncontrolling shareholders occurs based on the respective ownership percentages.

*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 compensation and related benefits, stock-based compensation, consulting fees, research and laboratory fees, rent of research facilities, amortization of intangible assets, and license fees paid to third parties to acquire patents or licenses to use patents and other technology. Research and development are expensed 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.

*General and administrative* – General and administrative expenses consist of compensation and related benefits, including stock-based compensation, for executive and corporate personnel; professional and consulting fees; and

allocated overhead such as facilities and equipment rent and maintenance, insurance costs allocated to general and administrative expenses, costs of patent applications, prosecution and maintenance, stock exchange-related costs, depreciation expense, marketing costs, and other miscellaneous expenses which are allocated to general and administrative expense.

*Foreign currency translation adjustments and other comprehensive income or loss* – In countries in which BioTime operates where the functional currency is other than the U.S. dollar, assets and liabilities are translated using published exchange rates in effect at the consolidated balance sheet date. Revenues and expenses and cash flows are translated using an approximate weighted average exchange rate for the period. Resulting foreign currency translation adjustments are recorded as other comprehensive income or loss, net of tax, in the consolidated statements of comprehensive income or loss and included as a component of accumulated other comprehensive income or loss on the consolidated balance sheets. Foreign currency translation adjustments are primarily attributable to Cell Cure and ESI, BioTime’s consolidated foreign subsidiaries. For the years ended December 31, 2018 and 2017, comprehensive income includes foreign currency translation adjustments, net of tax, of \$1.3 million and \$0.7 million, respectively.

*Foreign currency transaction gains and losses* – For transactions denominated in other than the functional currency of BioTime or its subsidiaries, BioTime recognizes transaction gains and losses in the consolidated statements of operations and classifies the gain or loss based on the nature of the item that generated it. The majority of BioTime’s foreign currency transaction gains and losses are generated by Cell Cure’s intercompany debt due to BioTime (see Notes 11 and 12), which are U.S. dollar-denominated, while Cell Cure’s functional currency is the Israeli New Shekel (“NIS”). At each balance sheet date, BioTime remeasures the intercompany debt using the current exchange rate at that date pursuant to ASC 830, *Foreign Currency Matters*. These foreign currency remeasurement gains and losses are included in other income and expenses, net.

*Income taxes* – BioTime accounts 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. BioTime files a U.S. federal income tax return as well as various state and foreign income tax returns. BioTime’s 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. If BioTime assumptions, and consequently the estimates, change in the future with respect to BioTime’s own deferred tax assets and liabilities, the valuation allowance may be increased or decreased, which may have a material impact on BioTime’s consolidated financial statements. BioTime recognizes accrued interest and penalties related to unrecognized tax benefits, if any, as income tax expense, however, no amounts were accrued for the payment of interest and penalties as of December 31, 2018 and 2017.

On December 22, 2017, the United States enacted major federal tax reform legislation, Public Law No. 115-97, commonly referred to as the 2017 Tax Cuts and Jobs Act (“2017 Tax Act”), which enacted a broad range of changes to the Internal Revenue Code. Changes to taxes on corporations impacted by the 2017 Tax Act include, among others, lowering the U.S. federal tax rates to a 21% flat tax rate, elimination of the corporate alternative minimum tax (“AMT”), imposing additional limitations on the deductibility of interest and net operating losses, allowing any net operating loss (“NOLs”) generated in tax years ending after December 31, 2017 to be carried forward indefinitely and generally repealing carrybacks, reducing the maximum deduction for NOL carryforwards arising in tax years beginning after 2017 to a percentage of the taxpayer’s taxable income, and allowing for the expensing of certain capital expenditures. The 2017 Tax Act also puts into effect a number of changes impacting operations outside of the United States including, but not limited to, the imposition of a one-time tax “deemed repatriation” on accumulated offshore earnings not previously subject to U.S. tax, and shifts the U.S. taxation of multinational corporations from a worldwide system of taxation to a territorial system. ASC 740 requires the effects of changes in tax rates and laws on deferred tax balances (including the effects of the one-time transition tax) to be recognized in the period in which the legislation is enacted (see Note 14).

For 2017, LifeMap Sciences included a deemed repatriation of \$227,000 in accumulated foreign earnings not previously subject to U.S. tax in federal income from LifeMap Sciences Ltd. The federal taxable income was offset by the LifeMap Sciences’ net operating loss carryforwards resulting in no federal income tax due.

Beginning in 2018, the 2017 Tax Act subjects a U.S. shareholder to tax on Global Intangible Low Tax Income (GILTI) earned by certain foreign subsidiaries. In general, GILTI is the excess of a U.S. shareholder’s total net foreign income over a deemed return on tangible assets. The provision further allows a deduction of 50% of GILTI, however this deduction is limited by the Company’s pre-GILTI U.S. income. For 2018, BioTime incurred a net loss from foreign activity, accordingly there was no GILTI inclusion in U.S. income. Current interpretations under ASC 740 state that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. BioTime has elected to account for GILTI as a current period expense

when incurred.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”) to provide guidance for companies that are not able to complete their accounting for the income tax effects of the 2017 Tax Act in the period of enactment. SAB 118 allows BioTime to record provisional amounts during a measurement period not to extend beyond one year of the enactment date (see Note 14). BioTime applied the guidance in SAB 118 when accounting for the enactment-date effects of the 2017 Tax Act during the years ended December 31, 2018 and 2017. As of December 31, 2018, BioTime completed its accounting for all the enactment-date income tax effects of the 2017 Tax Act.

Income tax benefit or expense for each year is allocated to continuing operations, other comprehensive income and the cumulative effects of accounting changes, if any, recorded directly to shareholders’ equity. ASC 740-20-45 *Income Taxes, Intra-period Tax Allocation, Other Presentation Matters* includes an exception to the general principle of intra-period tax allocations. The codification source states that the tax effect of pretax income or loss from continuing operations generally should be determined by a computation that considers only the tax effects of items that are included in continuing operations. The exception to that incremental approach is that all items, including items of other comprehensive income, be considered in determining the amount of tax benefit that results from a loss from continuing operations, and that benefit should be allocated to continuing operations. That is, when a company has a current period loss from continuing operations, management must consider income recorded in other categories in determining the tax benefit that is allocated to continuing operations. This includes situations in which a company has recorded a full valuation allowance at the beginning and end of the period, and the overall tax provision for the year is zero. The intra-period tax allocation is performed once the overall tax provision has been computed and allocates that provision to continuing operations and other comprehensive income and balance sheet captions. While the intra-period tax allocation does not change the overall tax provision, it results in a gross-up of the individual components. Additionally, different tax jurisdictions must be considered separately. For the year ended December 31, 2018, BioTime’s other comprehensive income is comprised entirely of foreign currency translation adjustments primarily attributable to its majority-owned and consolidated Israeli subsidiary, Cell Cure. For the year ended December 31, 2017, BioTime’s other comprehensive income or loss items were comprised of foreign currency translation adjustments and available-for-sale securities (see discussion under section *Marketable equity securities* for adoption of ASU 2016-01 on January 1, 2018) (see Note 14).



*Stock-based compensation* – BioTime follows accounting standards governing share-based payments in accordance with ASC 718, *Compensation – Stock Compensation*, which require the measurement and recognition of compensation expense for all share-based payment awards made to directors and employees, including employee stock options, based on estimated fair values. Upon adoption of ASU 2016-09 on January 1, 2017, forfeitures are accounted for as they occur instead of based on the number of awards that were expected to vest prior to adoption of ASU 2016-09. Based on the nature and timing of grants, straight line expense attribution of stock-based compensation for the entire award and the relatively low forfeiture rates on BioTime’s experience, the impact of adoption of ASU 2016-09 pertaining to forfeitures was not material to the consolidated financial statements. BioTime utilizes the Black-Scholes option pricing model for valuing share-based payment awards. BioTime’s determination of fair value of share-based payment awards on the date of grant using that option-pricing model is affected by BioTime’s stock price as well as by assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, BioTime’s expected stock price volatility over the term of the awards; the expected term of options granted, derived from historical data on employee exercises and post-vesting employment termination behavior; and a risk-free interest rate based on the U.S. Treasury rates in effect during the corresponding period of grant.

Certain of BioTime’s privately-held formerly consolidated subsidiaries have their own share-based compensation plans. For share-based compensation awards granted by those privately-held consolidated subsidiaries under their respective equity plans, BioTime determines the expected stock price volatility using historical prices of comparable public company common stock for a period equal to the expected term of the options. The expected term of privately-held subsidiary 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 the privately-held formerly consolidated subsidiaries is determined by the Board of Directors of those subsidiaries, as applicable, which is also used to determine the exercise prices of the stock options at the time of grant.

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.

*Basic and diluted net loss per share attributable to common shareholders* – Basic earnings per share is calculated by dividing net income or loss attributable to BioTime common shareholders by the weighted average number of common shares outstanding, net of unvested restricted stock or restricted stock units, subject to repurchase by BioTime, if any, during the period. Diluted earnings per share is calculated by dividing the net income or loss attributable to BioTime common shareholders by the weighted average number of common shares outstanding, adjusted for the effects of potentially dilutive common shares issuable under outstanding stock options and warrants, using the treasury-stock method, convertible preferred stock, if any, using the if-converted method, and treasury stock held by subsidiaries, if any.

For the years ended December 31, 2018 and 2017, because BioTime reported a net loss attributable to common stockholders, all potentially dilutive common stock is antidilutive.

The following common share equivalents were excluded from the computation of diluted net income (loss) per common share for the periods presented because including them would have been antidilutive (in thousands):

	Year Ended December 31,	
	2018	2017
Stock options and restricted stock units	14,269	7,983
Warrants	-	9,395
Treasury stock	-	81

*Recently adopted accounting pronouncements*

*Adoption of ASU 2016-18, Statement of Cash Flows (Topic 230)* – On January 1, 2018, BioTime adopted Financial Accounting Standards Board (“FASB”) ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents and restricted cash, and that restricted cash be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the condensed consolidated statements of cash flows. The adoption of ASU 2016-18 did not have a material effect on BioTime’s consolidated financial statements. However, prior period restricted cash balances included in prepaid expenses and other current assets, and in deposits and other long-term assets, on the consolidated balance sheets was added to the beginning-of-period and end-of-period total consolidated cash and cash equivalents in the consolidated statements of cash flows to conform to the current presentation shown below.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet dates that comprise the total of the same such amounts shown in the consolidated statements of cash flows for all periods presented herein and effected by the adoption of ASU 2016-18 (in thousands):

	December 31,		
	2018	2017	2016
Cash and cash equivalents	\$23,587	\$36,838	\$22,088
Restricted cash included in prepaid expenses and other current assets (see Note 15)	346	-	-
Restricted cash included in deposits and other long-term assets (see Note 15)	466	847	847
Total cash, cash equivalents, and restricted cash as shown in the consolidated statements of cash flows	\$24,399	\$37,685	\$22,935

*Adoption of ASU 2014-09, Revenues from Contracts with Customers (Topic 606)* – In May 2014, the FASB issued ASU 2014-09 (“Topic 606”) *Revenue from Contracts with Customers* which supersedes the revenue recognition requirements in Topic 605 *Revenue Recognition* (“Topic 605”). Topic 606 describes principles an entity must apply to measure and recognize revenue and the related cash flows, using the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. Topic 606 core principle is that it requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

BioTime adopted Topic 606 as of January 1, 2018 using the modified retrospective transition method applied to those contracts which were not completed as of the adoption date. Results for reporting periods beginning on January 1, 2018 and thereafter are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with BioTime’s historical revenue recognition accounting under Topic 605.

On January 1, 2018, the adoption and application of Topic 606 resulted in an immaterial cumulative effect adjustment to BioTime's beginning consolidated accumulated deficit balance. In the applicable paragraphs below, BioTime has summarized its revenue recognition policies for its various revenue sources in accordance with Topic 606.

*Revenue Recognition by Source and Geography* – Revenues are recognized when control of the promised goods or services is transferred to customers, or in the case of governmental entities funding a grant, when allowable expenses are incurred, in an amount that reflects the consideration BioTime or a subsidiary, depending on which company has the customer or the grant, expects to be entitled to in exchange for those goods or services. See further discussion under *Grant Revenues* below.

The following table presents BioTime's consolidated revenues disaggregated by source (in thousands).

	Year Ended December 31,	
REVENUES:	2018	<b>2017</b> (1)
Grant revenue	\$3,572	\$1,666
Royalties from product sales and license fees	392	389
Subscription and advertisement revenues (2)	691	1,395
Sale of research products and services	333	8
Total revenues	\$4,988	\$3,458

(1) Amounts recognized prior to adoption of Topic 606 have not been adjusted under the Topic 606 modified retrospective transition method.

(2) These revenues were generated by LifeMap Sciences, which is a subsidiary of AgeX, are included in BioTime consolidated revenues for the period from January 1, 2018 through August 29, 2018, the date immediately preceding the AgeX Deconsolidation. As a result of the AgeX Deconsolidation on August 30, 2018, BioTime does not expect to recognize subscription and advertisement revenues during subsequent accounting periods.

The following table presents consolidated revenues, disaggregated by geography, based on the billing addresses of customers, or in the case of grant revenues based on where the governmental entities that fund the grant are located (in thousands). See further discussion under *Grant Revenues* below.

	Year Ended December 31,	
REVENUES:	2018	<b>2017</b> (1)
United States	\$1,804	\$1,651
Foreign (2)	3,184	1,807
Total revenues	\$4,988	\$3,458

(1) Amounts recognized prior to adoption of Topic 606 have not been adjusted under the Topic 606 modified retrospective transition method.

(2) Foreign revenues are primarily generated from grants in Israel.

*Research and development contracts with customers* – In its agreements with customers, BioTime’s performance obligations of research and development are completed as services are performed and control passes to the customer, and accordingly revenues are recognized over time. BioTime generally receives a fee at the inception of an agreement, with variable fees, if any, tied to certain milestones, if achieved. BioTime estimates this variable consideration using a single most likely amount. Based on historical experience, there has been no variable consideration related to milestones included in the transaction price due to the significant uncertainty of achieving contract milestones and milestones not being met. If a milestone is met, subsequent changes in the single most likely amount may produce a different variable consideration, and BioTime will allocate any subsequent changes in the transaction price on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation will be recognized as revenue in the period in which the transaction price changes with respect to variable consideration, which could result in a reduction of revenue. Contracts of this kind are typically for a term greater than one year. For each of the years ended December 31, 2018 and 2017, BioTime recognized \$308,000 for such services included in the consolidated royalties from product sales and license fees. There were no deferred revenues related to unsatisfied performance obligations in the consolidated balance sheet as of December 31, 2018. As of December 31, 2018, BioTime had not met any milestones that would require adjustment of the transaction price.

*Royalties from product sales and license fees* – BioTime’s performance obligations in agreements with certain customers is to provide a license to allow customers to make, import and sell company licensed products or methods for pre-clinical studies and commercial use. Customers pay a combination of a license issue fee paid up front and a sales-based royalty, if any, in some cases with yearly minimums. The transaction price is deemed to be the license issue fee stated in the contract. The license offered by BioTime is a functional license with significant standalone functionality and provides customers with the right to use BioTime’s intellectual property. This allows BioTime to recognize revenue on the license issue fee at a point in time at the beginning of the contract, which is when the customer begins to have use of the license. Variable consideration related to sales-based royalties is recognized only when (or as) the later of the following events occurs: (a) a sale or usage occurs, or (b) the performance obligation to

which some, or all, of the sales-based or usage-based royalty has been allocated has been satisfied or partially satisfied. Due to the contract termination clauses, BioTime does not expect to receive all of the minimum royalty payments throughout the term of the agreements. Therefore, BioTime fully constrains recognition of the minimum royalty payments as revenues until its customers are obligated to pay, which is generally within 60 days prior to beginning of each year the minimum royalty payments are due. For the years ended December 31, 2018 and 2017, royalty revenues were immaterial.

*Sale of research products and services* – Revenues from the sale of research products and services shown in the table above are primarily derived from the sale of hydrogels and stem cell products for research use and are recognized when earned. These revenues are recognized at a point-in-time when control of the product transfers to the customer, which is typically upon shipment to the customer from the Alameda facility. Cost of sales from the sale of research products include direct and indirect overhead expenses incurred to purchase and manufacture those products, including lab supplies, personnel costs, freight, and royalties paid, if any, in accordance with the terms of applicable licensing agreements for those products.

Revenues from the sale of hydrogels and stem cell products, including the cost of sales related to those products, were immaterial for all periods presented.

*Subscription and advertisement revenues* – LifeMap Sciences, a direct majority-owned subsidiary of AgeX, sells subscription-based products, including research databases and software tools, for biomedical, gene, disease, and stem cell research. LifeMap Sciences sells these subscriptions primarily through the internet to biotech and pharmaceutical companies worldwide. LifeMap Sciences' principal subscription product is the GeneCard® Suite, which includes the GeneCards® human gene database, and the MalaCards™ human disease database.

LifeMap Sciences' performance obligations for subscriptions include a license of intellectual property related to its genetic information packages and premium genetic information tools. These licenses are deemed functional licenses that provide customers with a "right to access" to LifeMap Sciences' intellectual property during the subscription period and, accordingly, revenue is recognized over a period of time, which is generally the subscription period. Payments are typically received at the beginning of a subscription period and revenue is recognized according to the type of subscription sold.

For subscription contracts in which the subscription term commences before a payment is due, LifeMap Sciences records an accounts receivable as the subscription is earned over time and bills the customer according to the contract terms. LifeMap Sciences continuously monitors collections and payments from customers and maintains a provision for estimated credit losses and uncollectible accounts based upon its historical experience and any specific customer collection issues that have been identified. Amounts determined to be uncollectible are written off against the allowance for doubtful accounts. LifeMap Sciences has not historically provided significant discounts, credits, concessions, or other incentives from the stated price in the contract as the prices are offered on a fixed fee basis for the type of subscription package being purchased. LifeMap Sciences may issue refunds only if the packages cease to be available for reasons beyond its control. In such an event, the customer will get a refund on a pro-rata basis. Using the most likely amount method for estimating refunds under Topic 606, including historical experience, LifeMap Sciences determined that the single most likely amount of variable consideration for refunds is immaterial as LifeMap Sciences does not expect to pay any refunds. Both the customer and LifeMap Sciences expect the subscription packages to be available during the entire subscription period, and LifeMap Sciences has not experienced any significant issues with the availability of the product and has not issued any material refunds.

LifeMap Sciences performance obligations for advertising are overall advertising services and represent a series of distinct services. Contracts are typically less than a year in duration and the fees charged may include a combination of fixed and variable fees with the variable fees tied to click throughs to the customer's products on their website. LifeMap Sciences allocates the variable consideration to each month the click through services occur and allocates the annual fee to the performance obligation period of the initial term of the contract because those amounts correspond to the value provided to the customer each month. For click-through advertising services, at the time the variable compensation is known and determinable, the service has been rendered. Revenue is recognized at that time. The annual fee is recognized over the initial subscription period because this is a service and the customer simultaneously receives and consumes the benefit of LifeMap Sciences' performance.

LifeMap Sciences deferred subscription revenues primarily represent subscriptions for which cash payment has been received for the subscription term, but the subscription term has not been completed as of the balance sheet date reported. No revenues from subscription and advertisement products have been recorded since August 29, 2018 because of the AgeX Deconsolidation. The LifeMap Sciences revenues shown for the year ended December 31, 2018 are for revenues earned through August 29, 2018, the date immediately preceding the AgeX Deconsolidation. As a result of the AgeX Deconsolidation, BioTime does not expect to earn subscription and advertising revenues in subsequent accounting periods.

For the years ended December 31, 2018 and 2017, LifeMap Sciences recognized \$0.7 million and \$1.4 million, respectively, in subscription and advertisement revenues. As of December 31, 2018, there were no deferred revenues related to LifeMap Sciences included in the consolidated balance sheets due to the AgeX Deconsolidation on August 30, 2018.

LifeMap Sciences has licensed from a third party the databases it commercializes and has a contractual obligation to pay royalties to the licensor on subscriptions sold. These costs are included in cost of sales on the condensed consolidated statements of operations when the cash is received, and the royalty obligation is incurred as the royalty payments do not qualify for capitalization of costs to fulfill a contract under ASC 340-40, *Other Assets and Deferred Costs – Contracts with Customers*.

*Grant revenues* – In applying the provisions of Topic 606, BioTime has determined that government grants are out of the scope of Topic 606 because the government entities do not meet the definition of a “customer”, as defined by Topic 606, as there is not considered to be a transfer of control of good or services to the government entities funding the grant. BioTime has, and will continue to, account for grants received to perform research and development services in accordance with ASC 730-20, *Research and Development Arrangements*, which requires an assessment, at the inception of the grant, of whether the grant is a liability or a contract to perform research and development services for others. If BioTime or a subsidiary receiving the grant is obligated to repay the grant funds to the grantor regardless of the outcome of the research and development activities, then BioTime is required to estimate and recognize that liability. Alternatively, if BioTime or a subsidiary receiving the grant is not required to repay, or if it is required to repay the grant funds only if the research and development activities are successful, then the grant agreement is accounted for as a contract to perform research and development services for others, in which case, grant revenue is recognized when the related research and development expenses are incurred (see Note 15).



Deferred grant revenues represent grant funds received from the governmental funding agencies for which the allowable expenses have not yet been incurred as of the balance sheet date reported. As of December 31, 2018, deferred grant revenue was immaterial.

*Arrangements with multiple performance obligations* – BioTime’s contracts with customers may include multiple performance obligations. For such arrangements, BioTime allocates revenue to each performance obligation based on its relative standalone selling price. BioTime generally determines or estimates standalone selling prices based on the prices charged, or that would be charged, to customers for that product or service. As of, and for the year ended, December 31, 2018, BioTime did not have significant arrangements with multiple performance obligations.

*Adoption of ASU 2016-01, Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities* – Changes to the current GAAP model under ASU 2016-01 primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, ASU 2016-01 clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting for other financial instruments, such as loans, investments in debt securities, and financial liabilities is largely unchanged. The more significant amendments are to equity investments in unconsolidated entities. In accordance with ASU No. 2016-01, all equity investments in unconsolidated entities (other than those accounted for using the equity method of accounting) will generally be measured at fair value through earnings. There will no longer be an available-for-sale classification (changes in fair value reported in other comprehensive income) for equity securities with readily determinable fair values. As further discussed above under the *marketable equity securities* policy, BioTime adopted ASU 2016-01 on January 1, 2018.

*Recently Issued Accounting Pronouncements* – The following accounting standards, which are not yet effective, are presently being evaluated by BioTime to determine the impact that they might have on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for non-employee share-based payment transactions. The new standard expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018 (including interim periods within that fiscal year), with early adoption permitted. As BioTime does not have a significant number of nonemployee share-based awards, BioTime does not believe that the application of the new standard will have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)”, which requires lessees to recognize assets and liabilities for leases with lease terms greater than twelve months in the statement of financial position. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income

statement. ASU 2016-02 also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. The update is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that reporting period. Early adoption is permitted. In July 2018, the FASB issued ASU 2018-10 and ASU 2018-11. ASU 2018-10 provides certain areas for improvement in ASU 2016-02 and ASU 2018-11 provides an additional optional transition method by allowing entities to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. BioTime is completing its assessment of the impact the adoption of ASU 2016-02 will have on its consolidated financial statements. BioTime expects that most of its operating lease commitments will be subject to the new standard and recognized as right-of-use assets and operating lease liabilities upon the adoption of ASU 2016-02, which is expected to increase the total consolidated assets and total consolidated liabilities that it reports. BioTime will adopt the new standard on January 1, 2019 and plans to use the optional transition method allowed by ASU 2018-11.

### **3. Sale of Significant Ownership Interest in AgeX to Juvenescence Limited**

On August 30, 2018, BioTime entered into a Stock Purchase Agreement with Juvenescence Limited and AgeX Therapeutics, Inc., pursuant to which BioTime sold 14.4 million shares of the common stock of AgeX to Juvenescence for \$3.00 per share, or an aggregate purchase price of \$43.2 million (the "Purchase Price"). Juvenescence paid \$10.8 million of the Purchase Price at closing, issued an unsecured convertible promissory note dated August 30, 2018 in favor of BioTime for \$21.6 million (the "Promissory Note"), and paid \$10.8 million on November 2, 2018. The Stock Purchase Agreement contains customary representations, warranties and indemnities from BioTime relating to the business of AgeX, including an indemnity cap of \$4.3 million, which is subject to certain exceptions.

The Promissory Note bears interest at 7% per annum, with principal and accrued interest payable at maturity two years after the closing of the Juvenescence Transaction (August 30, 2020). The Promissory Note cannot be prepaid prior to maturity or conversion. On the maturity date, if a “Qualified Financing” (as defined below) has not occurred, BioTime will have the right, but not the obligation, to convert the principal balance of the Promissory Note and accrued interest then due into a number of Series A Preferred Shares of Juvenescence at a conversion price of \$15.60 per share. Upon the occurrence of a Qualified Financing on or before the maturity date, the principal balance of the Promissory Note and accrued interest will automatically convert into a number of shares of the class of equity securities of Juvenescence sold in the Qualified Financing, at the price per share at which the Juvenescence securities are sold in the Qualified Financing; and, if AgeX common stock is listed on a national securities exchange in the U.S., the number of shares of the class of equity securities issuable upon conversion may be increased depending on the market price of AgeX common stock. A Qualified Financing is generally defined as an underwritten initial public offering of Juvenescence equity securities in which gross proceeds are not less than \$50.0 million. The Promissory Note is not transferable, except in connection with a change of control of BioTime.

For the year ended December 31, 2018, BioTime recognized \$0.5 million in interest income on the Promissory Note. As of December 31, 2018, the Promissory Note principal and accrued interest balance was \$22.1 million.

#### *Shareholder Agreement*

As provided in the Purchase Agreement, BioTime and Juvenescence entered into a Shareholder Agreement, dated August 30, 2018, setting forth the governance, approval and voting rights of the parties with respect to their holdings of AgeX common stock, including rights of representation on the AgeX Board of Directors, approval rights, preemptive rights, rights of first refusal and co-sale and drag-along and tag-along rights for so long as either BioTime or Juvenescence continue to own at least 15% of the outstanding shares of AgeX common stock. Pursuant to the Shareholder Agreement, Juvenescence and BioTime have the right to designate two persons each to be appointed to the six-member AgeX Board of Directors, with the remaining two individuals to be independent of Juvenescence and BioTime. The number of authorized directors of AgeX has been increased to accommodate those appointments. Additionally, following Juvenescence’s payment of the second cash installment on November 2, 2018, Juvenescence has the right to designate an additional member of the AgeX Board of Directors. The size of the AgeX Board of Directors will be correspondingly increased.

In connection with the Juvenescence Transaction, the termination provision of the Shared Facilities Agreement (see Note 11) entitling AgeX or BioTime to terminate the agreement upon six months advance written notice was amended. Pursuant to the amendment, following the deconsolidation of AgeX from BioTime’s consolidated financial statements on August 30, 2018 (see Notes 4 and 11), each party retains the right to terminate the Shared Facilities Agreement at any time by giving the other party six months advance written notice, but BioTime may not do so prior to September 1, 2020.

Following the Juvenescence Transaction, Juvenescence owns 16.4 million shares of AgeX common stock representing 45.8% of AgeX's issued and outstanding shares of common stock and, following the AgeX Distribution on November 28, 2018 (see Note 4), BioTime owns 1.7 million shares of AgeX common stock representing 4.8% of AgeX's issued and outstanding shares of common stock. Accordingly, in accordance with the Shareholder Agreement, beginning on the AgeX Distribution date, BioTime has no right to designate any members to the AgeX Board of Directors.

#### **4. Deconsolidation and Distribution of AgeX**

##### *Deconsolidation of AgeX*

On August 30, 2018, BioTime sold 14.4 million shares of the common stock of AgeX to Juvenescence (see Note 3). Immediately before that sale, BioTime and Juvenescence owned 80.4% and 5.6%, respectively, of AgeX's outstanding common stock. Immediately following that sale, BioTime and Juvenescence owned 40.2% and 45.8%, respectively, of AgeX's outstanding common stock. As a result, on August 30, 2018, AgeX was no longer a subsidiary of BioTime and, as of that date, BioTime experienced a "loss of control" of AgeX, as defined by 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 of a 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 representing a majority of the voting power of the subsidiary's voting securities. All of these loss-of-control factors were present with respect to BioTime's ownership interest in AgeX as of August 30, 2018. Accordingly, BioTime has deconsolidated AgeX's consolidated financial statements and consolidated results from BioTime's consolidated financial statements and consolidated results effective on August 30, 2018, in accordance with ASC, 810-10-40-4(c).

In connection with the Juvenescence Transaction discussed in Note 3 and the AgeX Deconsolidation on August 30, 2018, in accordance with ASC 810-10-40-5, BioTime recorded a gain on deconsolidation of \$78.5 million, which includes a financial reporting gain on the sale of the AgeX shares of \$39.2 million (see Note 14), during the year ended December 31, 2018, included in other income and expenses, net, in the consolidated statements of operations.

#### *Distribution of AgeX Shares*

On November 28, 2018, BioTime distributed 12.7 million shares of AgeX common stock owned by BioTime to holders of BioTime common shares, on a pro rata basis, in the ratio of one share of AgeX common stock for every 10 BioTime common shares owned. The AgeX Distribution was accounted for at fair value as a dividend-in-kind in the aggregate amount of \$34.4 million. This amount was determined by valuing the 12.7 million shares of AgeX common stock distributed to BioTime shareholders at the \$2.71 per share closing price of AgeX common stock, as quoted on the NYSE American, on November 29, 2018, the first trading day of AgeX common stock. Since BioTime has an accumulated deficit in its consolidated shareholders' equity, the entire fair value of the AgeX Distribution was charged against common stock equity included in the consolidated statements of changes in shareholders' equity for the year ended December 31, 2018.

Immediately following the distribution, BioTime owned 1.7 million shares of AgeX common stock, all of which it still owns, and which represents approximately 4.8% of AgeX's outstanding common stock as of December 31, 2018 and which shares BioTime holds as marketable equity securities (see Note 2).

### **5. Deconsolidation of OncoCyte and Asterias**

#### *Deconsolidation of OncoCyte*

On February 17, 2017, OncoCyte issued 625,000 shares of OncoCyte common stock to certain investors upon exercise of warrants. The warrants were issued as part of OncoCyte's financing on August 29, 2016. As a result of the issuance of the 625,000 shares, beginning on February 17, 2017, BioTime owned less than 50% of OncoCyte's outstanding common stock and experienced a loss of control of OncoCyte under GAAP. Accordingly, BioTime deconsolidated OncoCyte's financial statements and results of operations from BioTime, effective February 17, 2017, in accordance with ASC, 810-10-40-4(c), referred to as the "OncoCyte Deconsolidation". For periods on and after February 17, 2017, BioTime is accounting for its retained noncontrolling investment in OncoCyte under the equity method of accounting and has elected the fair value option under ASC 825-10, *Financial Instruments* (see Note 6).

In connection with the OncoCyte Deconsolidation and in accordance with ASC 810-10-40-5, BioTime recorded a gain on deconsolidation of \$71.7 million which is included in other income and expenses, net, in the consolidated statements of operations for the year ended December 31, 2017.

BioTime held 14.7 million shares of OncoCyte common stock, or approximately 36.1% of OncoCyte outstanding common stock, as of December 31, 2018.

#### *Deconsolidation of Asterias*

On May 13, 2016, BioTime's percentage ownership of the outstanding common stock of Asterias declined below 50% and BioTime experienced a loss of control of Asterias under GAAP. Accordingly, BioTime deconsolidated Asterias financial statements and results of operations from BioTime (the "Asterias Deconsolidation"), effective May 13, 2016, in accordance with ASC, 810-10-40-4(c). For periods on and after May 13, 2016, BioTime is accounting for the retained noncontrolling interest in Asterias under the equity method of accounting and has elected the fair value option under ASC 825-10. (see Note 7)

In connection with the Asterias Deconsolidation and in accordance with ASC 810-10-40-5, BioTime recorded a gain on deconsolidation of \$49.0 million during the year December 31, 2016 included in other income and expenses, net, in the consolidated statements of operations.

BioTime held 21.7 million shares of Asterias common stock, or approximately 39.1% of Asterias outstanding common stock, as of December 31, 2018.

As discussed in Note 19, on March 8, 2019, the Asterias Merger was completed and Asterias became a wholly owned subsidiary of BioTime. BioTime will consolidate Asterias' operations and results with its operations and consolidated results beginning on March 8, 2019.

## **6. Equity Method of Accounting for Common Stock of OncoCyte, at Fair Value**

BioTime elected to account for its 14.7 million shares of OncoCyte common stock at fair value using the equity method of accounting beginning on February 17, 2017, the date of the OncoCyte Deconsolidation. The OncoCyte shares had a fair value of \$20.3 million as of December 31, 2018 and a fair value of \$68.2 million as of December 31, 2017, based on the \$1.38 and \$4.65 closing prices of OncoCyte common stock on the NYSE American on the applicable date.

All share prices are determined based on the closing price of OncoCyte common stock on the NYSE American on the applicable dates.

For the year ended December 31, 2018, BioTime recorded an unrealized loss of \$47.9 million on the OncoCyte shares due to the decrease in OncoCyte stock price from December 31, 2017 to December 31, 2018. The OncoCyte shares had a fair value of \$68.2 million as of December 31, 2017 and a fair value of \$71.2 million as of February 17, 2017, based on the \$4.65 per share and \$4.85 per share closing prices of OncoCyte common stock on those respective dates. For the year ended December 31, 2017, BioTime recorded an unrealized loss of \$2.9 million due to the decrease in the OncoCyte stock price from February 17, 2017 to December 31, 2017.

The condensed results of operations and condensed balance sheet information of OncoCyte are summarized below (in thousands):

**For the  
Period**

**January  
1, 2017**

**through**

**February  
16, 2017**

(1)

*Condensed Statement of Operations* <sup>(1)</sup>

Research and development expense	\$ 798
General and administrative expense	377
Sales and marketing expense	213
Loss from operations	(1,388)
Net loss	\$ (1,392)

(1) OncoCyte's condensed results of operations for the period from January 1, 2017 through February 16, 2017, the date immediately preceding the OncoCyte Deconsolidation, for the year ended December 31, 2017, shown in the table below, is included in the consolidated results of operations of BioTime, after intercompany eliminations, as applicable.

The following table summarizes OncoCyte results of operations for the full years ended December 31, 2018 and 2017 (in thousands).

<i>Condensed Statements of Operations</i>	Year Ended	
	December 31,	
	2018	2017
Research and development expense	\$6,506	\$7,174
General and administrative expense	6,153	9,232
Sales and marketing expense	1,681	2,443
Loss from operations	(14,340)	(18,849)
Net loss	\$(14,890)	\$(19,375)

<i>Condensed Balance Sheet information</i> <sup>(1)</sup>	December 31,	
	2018	2017
Current assets	\$8,642	\$8,528
Noncurrent assets	876	1,688
	\$9,518	\$10,216
Current liabilities	\$4,698	\$4,454
Noncurrent liabilities	534	1,359
Stockholders' equity	4,286	4,403
	\$9,518	\$10,216



The condensed balance sheet information of OncoCyte as of December 31, 2018 and 2017, is provided for (1) informational and comparative purposes only. OncoCyte was not included in BioTime's consolidated balance sheet as of December 31, 2018 and 2017 due to the OncoCyte Deconsolidation on February 17, 2017.

## 7. Equity Method of Accounting for Common Stock of Asterias, at Fair Value

BioTime elected to account for its 21.7 million shares of Asterias common stock at fair value using the equity method of accounting beginning on May 13, 2016, the date of the Asterias Deconsolidation. The Asterias shares had a fair value of \$13.5 million as of December 31, 2018 and a fair value of \$48.9 million as of December 31, 2017, based on the \$0.62 and \$2.25 closing prices of Asterias common stock on the NYSE American on the applicable date.

All share prices are determined based on the closing price of Asterias common stock on the NYSE American on the applicable dates.

For the year ended December 31, 2018, BioTime recorded an unrealized loss of \$35.4 million on the Asterias shares due to the decrease in Asterias stock price from December 31, 2017 to December 31, 2018. For the year ended December 31, 2017, BioTime recorded an unrealized loss of \$51.1 million on the Asterias shares due to the decrease in Asterias stock price from December 31, 2016 to December 31, 2017.

The following table summarizes Asterias results of operations for the full years ended December 31, 2018 and 2017 (in thousands).

<i>Condensed Statements of Operations</i>	Year Ended December 31,	
	2018	2017
Total revenue	\$812	\$4,042
Gross profit	588	3,877
Loss from operations	(21,605)	(33,251)
Net loss	\$(21,820)	\$(28,372)

<i>Condensed Balance Sheet information</i> <sup>(1)</sup>	December 31,	
	2018	2017
Current assets	\$8,793	\$22,716
Noncurrent assets	13,481	20,376
	\$22,274	\$43,092

Edgar Filing: BIOTIME INC - Form 10-K

Current liabilities	\$2,982	\$3,521
Noncurrent liabilities	2,241	6,028
Stockholders' equity	17,051	33,543
	\$22,274	\$43,092

The condensed balance sheet information of Asterias as of December 31, 2018 and 2017, is provided for (1) informational and comparative purposes only and was not included in BioTime's consolidated balance sheet as of December 31, 2018 and 2017 due to the Asterias Deconsolidation on May 13, 2016.

On November 7, 2018, BioTime announced it entered into a definitive agreement to acquire the remaining ownership interest in Asterias Biotherapeutics, Inc. that BioTime did not own in a stock-for-stock transaction pursuant to which Asterias shareholders will receive 0.71 shares of BioTime common stock for every share of Asterias common stock. As of December 31, 2018, BioTime owned approximately 39.1% of Asterias' outstanding common stock.

As discussed in Note 19, upon the completion of the Asterias Merger on March 8, 2019, Asterias ceased to exist as a public company, BioTime owns all of the outstanding shares of Asterias' common stock and BioTime will consolidate Asterias' operations and results with its operations and consolidated results beginning on March 8, 2019.

**8. Property and Equipment, Net**

At December 31, 2018 and 2017, property and equipment, net and construction in progress were comprised of the following (in thousands):

	December 31,	
	<b>2018</b> <sup>(1)</sup>	2017
Equipment, furniture and fixtures	\$3,842	\$4,255
Leasehold improvements	3,910	4,434
Accumulated depreciation and amortization	(3,185)	(3,156)
Property and equipment, net	4,567	5,533
Construction in progress	1,268	-
Property and equipment, net and construction in progress	\$5,835	\$5,533

(1) Reflects the effect of the AgeX Deconsolidation.

Property and equipment at December 31, 2018 and 2017 includes \$146,000 and \$151,000 financed by capital leases, respectively. Depreciation and amortization expense amounted to \$1.1 million and \$0.9 million for the years ended December 31, 2018 and 2017, respectively.

*Construction in progress*

Construction in progress of \$1.3 million as of December 31, 2018 entirely relates to the leasehold improvements made at Cell Cure's lease facilities in Jerusalem, Israel, primarily financed by the landlord (see Note 15). The leasehold improvements were substantially completed in December 2018 and the assets placed in service in January 2019.

**9. Intangible Assets, Net**

At December 31, 2018 and 2017, intangible assets, primarily consisting of acquired patents and accumulated amortization were as follows (in thousands):

December 31,

	2018 <sup>(1)</sup>	2017
Intangible assets	\$19,020	\$23,294
Accumulated amortization	(15,895)	(16,394)
Intangible assets, net	\$3,125	\$6,900

(1) Reflects the effect of the AgeX Deconsolidation.

BioTime amortizes its intangible assets over an estimated period of 10 years on a straight-line basis. BioTime recognized \$2.2 million and \$2.3 million in amortization expense of intangible assets during the years ended December 31, 2018 and 2017, respectively.

Amortization of intangible assets for periods subsequent to December 31, 2018 is as follows (in thousands):

Year Ended December 31,	Amortization Expense
2019	\$ 1,911
2020	1,124
2021	90
Total	\$ 3,125

**10. Accounts Payable and Accrued Liabilities**

At December 31, 2018 and 2017, accounts payable and accrued liabilities consist of the following (in thousands):

	December 31,	
	<b>2018</b>	2017
	(1)	
Accounts payable	\$2,359	\$938
Accrued liabilities	1,639	2,368
Accrued compensation	2,456	2,275
Other current liabilities	9	137
Total	\$6,463	\$5,718

(1) Reflects the effect of the AgeX Deconsolidation.

**11. Related Party Transactions***Shared Facilities and Service Agreements with Affiliates*

The receivables from affiliates shown on the consolidated balance sheets as of December 31, 2018 and 2017 primarily represent amounts owed to BioTime by OncoCyte and AgeX under separate and respective Shared Facilities and Service Agreements (each a “Shared Facilities Agreement”), with amounts owed by OncoCyte comprising most of that amount. Under the terms of the Shared Facilities Agreements, BioTime allows OncoCyte and AgeX to use BioTime’s premises and equipment located at BioTime’s headquarters in Alameda, California for the purpose of conducting business. BioTime also provides accounting, billing, bookkeeping, payroll, treasury, payment of accounts payable, and other similar administrative services to OncoCyte and AgeX. BioTime may also provide the services of attorneys, accountants, and other professionals who may provide professional services to BioTime and its other subsidiaries. BioTime also has provided OncoCyte and AgeX with the services of laboratory and research personnel, including BioTime employees and contractors, for the performance of research and development work for OncoCyte and AgeX at the premises.

BioTime charges OncoCyte and AgeX a “Use Fee” for services provided and for use of BioTime facilities, equipment, and supplies. For each billing period, BioTime prorates and allocates to OncoCyte and AgeX costs incurred, including costs for services of BioTime employees and use of equipment, insurance, leased space, professional services, software licenses, supplies and utilities. The allocation of costs depends on key cost drivers, including actual documented use, square footage of facilities used, time spent, costs incurred by BioTime for OncoCyte and AgeX, or

upon proportionate usage by BioTime, OncoCyte and AgeX, as reasonably estimated by BioTime. BioTime, at its discretion, has the right to charge OncoCyte and AgeX a 5% markup on such allocated costs. The allocated cost of BioTime employees and contractors who provide services is based upon the number of hours or estimated percentage of efforts of such personnel devoted to the performance of services.

The Use Fee is determined and invoiced to OncoCyte and AgeX on a regular basis, generally monthly or quarterly. Each invoice is payable in full within 30 days after receipt. Any invoice, or portion thereof, not paid in full when due will bear interest at the rate of 15% per annum until paid, unless the failure to make a payment is due to any inaction or delay in making a payment by BioTime. Through December 31, 2018, BioTime has not charged OncoCyte or AgeX any interest.

In addition to the Use Fee, OncoCyte or AgeX reimburse BioTime for any out of pocket costs incurred by BioTime for the purchase of office supplies, laboratory supplies, and other goods and materials and services for the account or use of OncoCyte or AgeX. BioTime is not obligated to purchase or acquire any office supplies or other goods and materials or any services for OncoCyte or AgeX, and if any such supplies, goods, materials or services are obtained, BioTime may arrange for the suppliers to invoice OncoCyte or AgeX directly.

The Shared Facilities Agreements remain in effect until a party gives the other party written notice that the Shared Facilities Agreement will terminate on December 31 of that year, or unless it is otherwise terminated under another provision of the agreement. In addition, BioTime and AgeX may each terminate their Shared Facilities Agreement prior to December 31 of the year by giving the other party written six months' notice to terminate, but BioTime may not do so prior to September 1, 2020.

In the aggregate, BioTime charged Use Fees to OncoCyte and AgeX as follows (in thousands):

	Year Ended	
	December 31,	
	2018	2017
Research and development	\$1,378	\$1,085
General and administrative	790	557
Total use fees	\$2,168	\$1,642

The Use Fees charged to OncoCyte and AgeX shown above are not reflected in revenues, but instead BioTime's general and administrative expenses and research and development expenses are shown net of those charges in the consolidated statements of operations. As of December 31, 2018 and 2017, BioTime has a \$2.1 million receivable from OncoCyte included in receivable from affiliates, net, on account of Use Fees incurred by OncoCyte under the Shared Facilities Agreement (see Note 19). As of December 31, 2018, BioTime has an immaterial amount receivable from AgeX included in receivable from affiliates, net, on account of Use Fees incurred by AgeX, while amounts owed to BioTime as of December 31, 2017 were eliminated in consolidation with BioTime as of that date. Since these amounts are due and payable within 30 days of being invoiced, the receivable is classified as a current asset.

BioTime accounts for receivables from affiliates, net of payables to affiliates, if any, for similar shared services and other transactions BioTime's consolidated subsidiaries may enter into with nonconsolidated affiliates. BioTime and the affiliates record those receivables and payables on a net basis since BioTime and the affiliates intend to exercise a right of offset of the receivable and the payable and to settle the balances net by having the party that owes the other party pay the net balance owe.

#### *Related Party Convertible Debt*

Cell Cure issued certain convertible promissory notes (the "Convertible Notes") to Cell Cure shareholders other than BioTime. The Convertible Notes bear a stated interest rate of 3% per annum. The total outstanding principal balance of the Convertible Notes, with accrued interest, were due and payable on various maturity dates in July 2017 and September 2017, and in February 2019 through August 2019. The outstanding principal balance of the Convertible Notes with accrued interest was convertible into Cell Cure ordinary shares at a fixed conversion price of \$20.00 per share, at the election of the holder, at any time prior to maturity. Any conversion of the Convertible Notes was required to be settled with Cell Cure ordinary shares and not with cash. The conversion feature of the Convertible Notes issued was not accounted for as an embedded derivative under the provisions of ASC 815, *Derivatives and Hedging* since it was not a freestanding financial instrument and the underlying Cell Cure ordinary shares are not readily convertible into cash. Accordingly, the Convertible Notes were accounted for under ASC 470-20, *Debt with Conversion and Other Options* (ASC 470-20). Under ASC 470-20, BioTime determined that a beneficial conversion feature ("BCF") was present on the issuance dates of the Convertible Notes. A conversion feature is beneficial if, on the issuance dates, the effective conversion price is less than the fair value of the issuer's capital stock. Since the effective

conversion price of \$20.00 per share is less than the estimated range of fair values from \$28.00 per share to \$40.00 per share of Cell Cure ordinary shares on the dates the Convertible Notes were issued, a beneficial conversion feature, equal to the intrinsic value ranging from \$8 per share to \$20 per share, was present. In accordance with ASC 470-20-30-8, if the intrinsic value of the BCF is greater than the proceeds allocated to the convertible instrument, the amount of the discount assigned to the BCF is limited to the amount of the proceeds allocated to the convertible instrument. The BCF was recorded as an addition to equity with a corresponding debt discount on the Convertible Notes issuance date. This debt discount was amortized to interest expense using the effective interest method over the term of the debt, generally three years, representing an approximate effective annual interest rate between 11% and 23%.

In July 2017, BioTime purchased all of the outstanding Convertible Notes and Cell Cure ordinary shares held by HBL, a Cell Cure shareholder that owned substantially all the Convertible Notes and 21.2% of the outstanding Cell Cure ordinary shares (see Note 12). BioTime purchased such Convertible Notes in exchange for 2,776,662 shares of BioTime common stock valued at \$8.6 million, and purchased such Cell Cure ordinary shares in exchange for 1,220,207 shares of BioTime common stock valued at \$3.8 million. The value of the BioTime common stock was determined based on the closing price of BioTime common stock on the NYSE American on July 10, 2017, or \$3.09 per share (see Note 12).

The purchase of the Convertible Notes from HBL was accounted for as an extinguishment of a convertible debt with a beneficial conversion feature under ASC 470-50-40, *Debt – Modifications and Extinguishments*. This guidance requires an entity to recognize the difference between the reacquisition price and the net carrying value of the extinguished debt, including any unamortized discount relating to the BCF, as a gain or loss on extinguishment in the statement of operations. The entity must also calculate the intrinsic value, if any, of the conversion option of the debt and charge this amount to equity and allocate the remainder of the reacquisition price to the extinguishment of the debt and record a gain or loss on debt extinguishment by comparing the reacquisition price allocated to the debt with the net carrying value amount of the debt.



In connection with the purchase of the Convertible Notes from HBL, and in accordance with ASC 470-50-40, BioTime recorded a charge to equity of \$3.1 million representing the intrinsic value of the conversion option of the Convertible Notes, and a \$2.8 million noncash loss on debt extinguishment included in other income and expenses, net, during the year ended December 31, 2017.

*Other related party transactions*

In connection with the capitalization of AgeX in August 2017 (see Note 12), Alfred D. Kingsley, the Chairman of BioTime's Board of Directors, purchased 200,000 shares of AgeX common stock. The AgeX shares were sold to Mr. Kingsley on the same terms (including price, \$2.00 per share) as such shares were sold to other investors in that transaction.

In August 2017, Mr. Kingsley acquired an additional 421,500 AgeX shares valued at \$2.00 per share from BioTime in exchange for 300,000 BioTime common shares owned by Mr. Kingsley valued at \$2.81 per share.

BioTime currently pays \$5,050 per month for the use of approximately 900 square feet of office space in New York City, which is made available to BioTime on a month-by-month basis by one of its directors at an amount that approximates his cost.

## **12. Shareholders' Equity**

*Preferred Shares*

BioTime is authorized to issue 2,000,000 shares of preferred stock. The preferred shares may be issued in one or more series as the board of directors may by resolution determine. The board of directors is authorized to fix the number of shares of any series of preferred shares and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed on the preferred shares as a class, or upon any wholly unissued series of any preferred shares. The board of directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of preferred shares subsequent to the issue of shares of that series. As of December 31, 2018, no shares of preferred stock were issued or outstanding.

*Common Shares*

At December 31, 2018, BioTime was authorized to issue 250,000,000 common shares, no par value. As of December 31, 2018 and 2017, BioTime had 127,135,774 and 126,865,634 issued and outstanding common shares, respectively (see Note 19).

During the year ended December 31, 2018, BioTime issued 270,000 shares of common stock, net of shares withheld and retired for employee taxes paid, for vested restricted stock units (see Note 13).

In October 2017, BioTime completed a public offering of 11,057,693 common shares at a price of \$2.60 per share, including the underwriters' full exercise of their over-allotment option to purchase additional shares. The public offering generated net proceeds to BioTime of approximately \$26.7 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by BioTime.

In July 2017, BioTime issued 4,924,542 common shares valued at \$15.2 million to purchase outstanding Convertible Notes and Cell Cure ordinary shares from HBL as further described in Note 11 and *Transactions with Noncontrolling Interests of Cell Cure* section below, respectively.

In April 2017, BioTime entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor Fitzgerald"), pursuant to which BioTime may offer and sell, from time to time, through Cantor Fitzgerald, shares of BioTime common stock having an aggregate offering price of up to \$25,000,000. BioTime is not obligated to sell any shares under the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations, and the rules of the NYSE American, to sell the shares from time to time based upon BioTime's instructions, including any price, time or size limits specified by BioTime. Under the Sales Agreement, Cantor Fitzgerald may sell the shares by any method deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or by any other method permitted by law, including in privately negotiated transactions. Cantor Fitzgerald's obligations to sell the shares under the Sales Agreement are subject to satisfaction of certain conditions, including the continued effectiveness of BioTime's Registration Statement on Form S-3 which became effective on May 5, 2017. As of December 31, 2018, \$24.2 million remained available for sale through the Sales Agreement under the Registration Statement.

BioTime will pay Cantor Fitzgerald a commission of 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Cantor Fitzgerald with customary indemnification and contribution rights. The Sales Agreement may be terminated by Cantor Fitzgerald or BioTime at any time upon notice to the other party, or by Cantor Fitzgerald at any time in certain circumstances, including the occurrence of a material and adverse change in BioTime's business or financial condition that makes it impractical or inadvisable to market the shares or to enforce contracts for the sale of the shares.

In connection with the capitalization of AgeX in August 2017, BioTime acquired 300,000 BioTime common shares from Alfred D. Kingsley in exchange for 421,500 shares of AgeX common stock owned by BioTime, as discussed in Note 11, and BioTime sold 300,000 common shares under the Sales Agreement to an unaffiliated and existing BioTime investor for \$2.81 per share. The BioTime common shares received from Mr. Kingsley were immediately retired as authorized but unissued shares (see Note 11). Although the transaction between Mr. Kingsley and BioTime was an exchange of shares, the proceeds from the sale of BioTime shares to the unrelated investor and the BioTime shares acquired from Mr. Kingsley are presented gross as separate cash items on the Consolidated Statements of Cash Flows for the year ended December 31, 2017, in accordance with ASC 230-10-45, *Statement of Cash Flows – Other Presentation Matters*.

In February 2017, BioTime sold 7,453,704 common shares in an underwritten public offering. The offering price to the public was \$2.70 per share and net proceeds to BioTime were approximately \$18.5 million, after deducting underwriting discounts, commissions and expenses related to the financing.

#### *BioTime Warrants*

BioTime has issued equity-classified warrants to purchase its common shares. Activity related to warrants in 2018 and 2017 is presented in the table below (in thousands, except price per share):

	Number of Warrant Shares	Per Share Exercise Price	Weighted Average Exercise Price
Outstanding, January 1, 2017	9,395	\$ 4.55	\$ 4.55
Expired in 2017	-		
Outstanding, December 31, 2017	9,395	\$ 4.55	\$ 4.55
Expired in 2018	(9,395)	4.55	
Outstanding, December 31, 2018	-	\$ -	\$ -

#### *Transactions with Noncontrolling Interests of AgeX Therapeutics, Inc.*

AgeX was incorporated in January 2017 for the purpose of acquiring and developing BioTime technology relating to cell immortality and regenerative biology by developing products for the treatment of aging and age-related diseases. Initial product development plans included: pluripotent stem cell-derived brown adipocytes (AGEX-BAT1); vascular progenitors (AGEX-VASC1); and induced Tissue Regeneration (iTR). Initial planned indications for these products are type II diabetes, cardiac ischemia, and cancer, respectively.

In August 2017, AgeX received its initial assets and cash from BioTime and certain investors. BioTime contributed certain assets and cash to AgeX in exchange for 28,800,000 shares of AgeX common stock pursuant to an Asset Contribution and Separation Agreement. BioTime and AgeX also entered into a License Agreement pursuant to which BioTime licensed or sublicensed to AgeX, and AgeX granted to BioTime an option to license back, certain patent rights. Concurrently with the BioTime's contribution of assets to AgeX, AgeX sold 4,950,000 shares of its common stock for \$10.0 million in cash primarily to investors, which included the Chairman of BioTime's Board of Directors (see Note 11). At the close of the financing and as of December 31, 2017, BioTime owned 85.4% of the outstanding shares of AgeX common stock.

In June 2018, AgeX sold 2.0 million shares of common stock to Juvenescence for \$2.50 per share for aggregate cash proceeds to AgeX of \$5.0 million. As of the completion of this financing, BioTime owned 80.6% of the outstanding shares of AgeX common stock and retained a controlling interest in AgeX. In August 2018 and prior to the AgeX Deconsolidation, AgeX issued 80,000 shares of AgeX common stock valued at \$0.2 million for certain assets AgeX acquired from a third party, decreasing BioTime's ownership interest to 80.4% of the outstanding shares of AgeX common stock. In connection with these transactions, BioTime recorded a \$3.8 million net proportional equity transfer, at carrying value, from noncontrolling interests in AgeX to BioTime in accordance with ASC 810-10-45-23, included in consolidated shareholders' equity for the year ended December 31, 2018.

In August 2018, BioTime sold 14,400,000 shares of AgeX common stock it owned to Juvenescence. Immediately after that sale, BioTime owned 40.2% of the outstanding shares of AgeX common stock, resulting in the AgeX Deconsolidation (see Notes 3 and 4).

#### *Transactions with Noncontrolling Interests of Cell Cure*

On July 10, 2017, BioTime purchased all of the outstanding Cell Cure Convertible Notes and Cell Cure ordinary shares held by HBL, a former Cell Cure shareholder that owned 21.2% of the issued and outstanding Cell Cure ordinary shares and substantially all of the Cell Cure Convertible Notes issued by Cell Cure shareholders other than BioTime (see Note 11). On the same date, BioTime also purchased all of the Cell Cure ordinary shares owned by Teva Pharmaceutical Industries, Ltd. (“Teva”), a former Cell Cure shareholder that owned 16.1% of the issued and outstanding Cell Cure ordinary shares. Teva did not have any Cell Cure Convertible Notes. To acquire the Cell Cure ordinary shares from HBL and Teva, BioTime issued 1,220,207 and 927,673 common shares, valued at \$3.8 million and \$2.8 million, to HBL and Teva, respectively, based on the closing price of BioTime common shares on the NYSE American. Prior to the consummation of the transactions with HBL and Teva, BioTime held 62.5% of the issued and outstanding Cell Cure ordinary shares and upon the consummation of the transactions BioTime held 99.8%. Accordingly, BioTime recorded a corresponding charge to equity of \$10.1 million and a proportional transfer of carrying value of \$3.5 million for purchase of noncontrolling interests in Cell Cure, included in the consolidated statement of shareholders’ equity for the year ended December 31, 2017, in accordance with ASC 810-10-45-23.

In October 2017, an unaffiliated third party exercised stock options to purchase 4,400 Cell Cure ordinary shares, reducing BioTime’s ownership from 99.8% to 98.8% of outstanding Cell Cure ordinary shares.

In May 2018, BioTime purchased 937 shares of Cell Cure ordinary shares for \$40.5359 per share, the same Cell Cure price per ordinary share paid by BioTime to each of HBL and Teva discussed above, resulting in an increase in BioTime’s ownership from 98.8% to 99.0%. Accordingly, BioTime recorded a \$1.9 million net proportional equity transfer, at carrying value, from noncontrolling interests in Cell Cure to BioTime included in consolidated shareholders’ equity for the year ended December 31, 2018, in accordance with ASC 810-10-45-23.

#### *Cell Cure Warrants – Liability Classified*

In July 2017, as an inducement to HBL to sell their Cell Cure ordinary shares to BioTime, Cell Cure issued warrants to HBL (the “HBL Warrants”) to purchase up to 24,566 Cell Cure ordinary shares at an exercise price of \$40.5359 per share, payable in U.S. dollars, the same Cell Cure price per ordinary share paid by BioTime to each of HBL and Teva for the purchase of their Cell Cure ordinary shares discussed above. No warrants were issued to Teva. The HBL Warrants are immediately exercisable and expire on the earliest of the lapse of 5 years from the issuance date or

immediately prior to the closing of a Corporate Transaction or an initial public offering, as defined in the HBL Warrant Agreement. For the year ended December 31, 2017, Cell Cure recorded a noncash expense of \$0.6 million included in general and administrative expenses in connection with the issuance of the HBL Warrants.

Cell Cure also has issued warrants to purchase up to 13,738 Cell Cure ordinary shares at exercise prices ranging from \$32.02 to \$40.00 per share, payable in U.S. dollars, to consultants (the “Consultant Warrants”), expiring in October 2020 and January 2024. The HBL Warrants and the Consultant Warrants are collectively referred to as the “Cell Cure Warrants”.

ASC 815 requires freestanding financial instruments, such as warrants, with exercise prices denominated in currencies other than the functional currency of the issuer to be accounted for as liabilities at fair value, with all subsequent changes in fair value after the issuance date to be recorded as gains or losses in the consolidated statements of operations. Because the exercise price of the Cell Cure Warrants is U.S. dollar-denominated and settlement is not expected to occur in the next twelve months, Cell Cure classified the Cell Cure Warrants as a long-term liability in accordance with ASC 815.

The fair value of the Cell Cure Warrants at the time of issuance was determined by using the Black-Scholes option pricing model using the respective contractual term of the warrants. In applying this model, the fair value is determined by applying Level 3 inputs, as defined by ASC 820; these inputs are based on certain key assumptions including the fair value of the Cell Cure ordinary shares, adjusted for lack of marketability, as appropriate, and the expected stock price volatility over the term of the Cell Cure Warrants. The fair value of the Cell Cure ordinary shares is determined by Cell Cure’s Board of Directors, which may engage a valuation specialist to assist it in estimating the fair value, or may use recent transactions in Cell Cure shares, if any, as a reasonable approximation of fair value, or may apply other reasonable methods to determining the fair value, including a discount for lack of marketability. BioTime determines the stock price volatility using historical prices of comparable public company common stock for a period equal to the remaining term of the Cell Cure Warrants. The Cell Cure Warrants are revalued each reporting period using the same methodology described above, with changes in fair value included as gains or losses in other income and expenses, net, in the consolidated statements of operations. Changes in any of the key assumptions used to value the Cell Cure Warrants could materially impact the fair value of the Cell Cure Warrants and BioTime’s consolidated financial statements.

For the year ended December 31, 2018, BioTime recorded a noncash gain of \$0.4 million for the decrease in the fair value of the Cell Cure Warrants included in other income and expenses, net. The decrease in the fair value of the Cell Cure Warrants was mainly attributable to the reduced remaining life of the warrants from the prior period, and management's assumption on the lack of marketability discount adjustment on the fair value of Cell Cure ordinary shares. As of December 31, 2018 and 2017, the Cell Cure Warrants, valued at \$0.4 million and \$0.8 million, respectively, were included in long-term liabilities on the consolidated balance sheets.

#### *Transactions with Noncontrolling Interests of Other Subsidiaries*

In June 2017, BioTime increased its ownership in LifeMap Sciences from 78% to 82% and obtained a direct 100% ownership interest in LifeMap Solutions, of which 78% was previously indirectly owned by BioTime through LifeMap Sciences, for settlement and cancellation of certain intercompany debt owed by LifeMap Sciences.

In 2017, certain OrthoCyte option holders exercised stock options to purchase 51,000 shares of OrthoCyte common stock, reducing BioTime's ownership from 100% to 99.8% of the outstanding shares of OrthoCyte common stock.

In August 2017, pursuant to the Asset Contribution Agreement between BioTime and AgeX discussed above, BioTime contributed its direct ownership in ReCyte Therapeutics and LifeMap Sciences to AgeX, and after the contribution BioTime owned these subsidiaries indirectly through its ownership of AgeX (which was 85.4% as of December 31, 2017).

The above described transactions were between entities under common control and the changes in ownership interests did not result in a change of control under GAAP. Accordingly, BioTime recorded a \$5.5 million net proportional equity transfer, at carrying values, from noncontrolling interests in these subsidiaries to BioTime included in consolidated shareholders' equity for the year ended December 31, 2017, in accordance with ASC 810-10-45-23.

### **13. Stock-Based Awards**

During December 2012, BioTime's Board of Directors approved the 2012 Equity Incentive Plan (the "2012 Plan"), which was amended during 2017, under which BioTime has reserved 16,000,000 common shares for the grant of stock options or the sale of restricted stock or other equity awards. No options may be granted under the 2012 Plan more than ten years after the date upon which the 2012 Plan was adopted by the Board of Directors, and no options granted under the 2012 Plan may be exercised after the expiration of ten years from the date of grant. Under the 2012 Plan, options to purchase common shares may be granted to employees, directors and certain consultants at prices not

less than the fair market value at date of grant, subject to certain limited exceptions for options granted in substitution of other options. Options may be fully exercisable immediately or may be exercisable according to a schedule or conditions specified by the Board of Directors or the Compensation Committee of the Board of Directors. The 2012 Plan also permits BioTime to award restricted stock for services rendered or to sell common shares to employees subject to vesting provisions under restricted stock agreements that provide for forfeiture of unvested shares upon the occurrence of specified events under a restricted stock award agreement. BioTime may permit employees or consultants, but not officers or directors, who purchase stock under restricted stock purchase agreements, to pay for their shares by delivering a promissory note that is secured by a pledge of their shares.

BioTime may also grant stock appreciation rights (“SARs”) and hypothetical units issued with reference to BioTime common shares (“RSUs”) under the 2012 Plan. A SAR is the right to receive, upon exercise, an amount payable in cash or shares or a combination of cash and shares, as determined by the Board of Directors or the Compensation Committee, equal to the number of shares subject to the SAR that is being exercised multiplied by the excess of (a) the fair market value of a BioTime common share on the date the SAR is exercised, over (b) the exercise price specified in the SAR award agreement.

The terms and conditions of a grant of RSUs will be determined by the Board of Directors or Compensation Committee. No shares of stock will be issued at the time an RSU is granted, and BioTime will not be required to set aside a fund for the payment of any such award. RSU recipients have no voting rights with respect to the shares underlying the RSU. Upon the expiration of the restrictions applicable to an RSU, BioTime will either issue to the recipient, without charge, one common share per RSU or cash in an amount equal to the fair market value of one common share. RSUs granted from the 2012 Plan reduce the shares available for grant by two shares for each RSU granted.



The following table summarizes consolidated stock-based compensation expense, including equity awards by privately-held consolidated subsidiaries, related to stock options and other equity awards for the years ended December 31, 2018 and 2017, which was allocated as follows (in thousands):

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
Research and development	\$785	\$932
General and administrative	4,617	3,000
Total stock-based compensation expense	\$5,402	\$3,932

As of December 31, 2018, total unrecognized compensation costs related to unvested stock options under BioTime's 2002 Plan and 2012 Plan was \$6.3 million, which is expected to be recognized as expense over a weighted average period of approximately 2.6 years.

The weighted-average estimated fair value of stock options granted under the 2012 Plan and other stock option awards granted outside of the 2012 Plan, during the years ended December 31, 2018 and 2017 was \$1.24 and \$1.65 per share respectively, using the Black-Scholes option pricing model with the following weighted-average assumptions:

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
Expected life (in years)	5.56	5.55
Risk-free interest rates	2.76%	1.83%
Volatility	56.07%	58.76%
Dividend yield	-%	-%

#### *Options and RSU Adjustment*

In connection with the AgeX Distribution discussed in Note 4 and in accordance with the provisions of the 2012 Plan and awards granted outside of the 2012 Plan, BioTime awards issued and outstanding as of November 28, 2018 were adjusted to maintain the intrinsic value of those awards immediately prior to and following the AgeX Distribution shown below. The adjustments to the number of shares subject to each RSU, stock option and the option exercise prices were based on the relative market capitalization of BioTime and AgeX as of the AgeX Distribution date. Since the adjustments were done to maintain intrinsic value of the BioTime options and RSUs in accordance with the 2012 Plan and awards issued outside of the 2012 Plan, there was no modification in accordance with ASC 718.

*General Option Information*

A summary of the 2012 Plan activity and other stock option awards granted outside of the 2012 Plan related information is as follows (in thousands except weighted average exercise price):

	Shares Available for Grant	Number of Options Outstanding	Number of RSUs Outstanding	Weighted Average Exercise Price
January 1, 2017	2,894	6,958	100	\$ 3.60
Increase to option pool	6,000	-		
Temporary restriction by Board on available pool <sup>(1)</sup>	(5,000)	-		
Granted under 2012 Plan	(1,954)	1,954		3.04
Exercised	-	(9)		2.66
Forfeited/cancelled/expired under 2012 Plan	545	(860)		4.43
RSU vesting	-	-	(38)	
December 31, 2017	2,485	8,043	62	\$ 3.38
Board mandated restriction restored <sup>(1)</sup>	5,000	-		
Exchange of options with Cell Cure <sup>(2)</sup>	(866)	866		2.16
Restricted stock units granted <sup>(3)</sup>	(1,586)	-	793	n/a
Inducement option grant <sup>(4)</sup>	-	1,500		2.31
Granted under 2012 Plan	(1,559)	1,559		2.84
Forfeited/cancelled/expired under 2012 Plan	731	(750)		3.33
Adjustment due to the AgeX Distribution <sup>(5)</sup>	(2,294)	2,294		n/a
Adjustment to inducement options due to the AgeX Distribution <sup>(5)</sup>	-	355		
Adjustment to restricted stock units due to the AgeX Distribution <sup>(5)</sup>	(272)		136	n/a
Restricted stock units vested	-		(466)	n/a
Restricted stock units expired unvested	246		(123)	n/a
December 31, 2018	1,885	13,867	402	\$ 2.44

The disclosures below regarding share-based awards that were granted on or before November 28, 2018 are before the applicable adjustments made to such awards to maintain intrinsic value before and after the AgeX Distribution, as discussed above.

<sup>(1)</sup>On October 13, 2017, BioTime's Board of Directors determined to temporarily set a 5.0 million total share limit on shares available for the grant of share-based awards pursuant to the 2012 Plan. As of December 31, 2017, the total 2.5 million shares available for grant was net of this 5.0 million share restriction. On May 4, 2018, BioTime's Board of Directors removed this restriction, thereby increasing shares available for the grant of share-based awards pursuant to the 2012 Plan.

<sup>(2)</sup> On July 9, 2018, BioTime's Board of Directors terminated the Cell Cure Equity Incentive Plan (the "Cell Cure Plan"), under which Cell Cure employees and certain consultants ("Cell Cure Option Holders") held outstanding options to purchase shares of common stock in Cell Cure, and BioTime granted the Cell Cure Option Holders BioTime options of equivalent value under the 2012 Plan in exchange for their Cell Cure options (the "BioTime Exchange"). The BioTime Exchange resulted in 866,000 grants of BioTime stock options under the 2012 Plan, all issued with an exercise price of \$2.16 per share to the Cell Cure Option Holders, based on BioTime's closing stock price on July 9,

2018. Of the total options granted under the BioTime Exchange, 275,000 are subject to continued service-based vesting from the original terms under the Cell Cure Plan, and 591,000 were immediately vested on the exchange date to reflect the fact that the Cell Cure Options Holders held prior to the exchange were already vested. Equivalent value of the BioTime Exchange was determined using the Black-Scholes option pricing model. The BioTime Exchange was accounted for as a modification under ASC 718, and BioTime recorded a noncash stock-based compensation expense of \$298,000 for the year ended December 31, 2018 included in consolidated stock-based compensation expense.

<sup>(3)</sup>On May 24, 2018 and August 10, 2018, BioTime granted 485,000 and 8,000 RSUs, respectively, to employees. The RSUs vest in increments upon the attainment of specified performance conditions, as determined by BioTime's Board of Directors, including the completion of the AgeX Distribution and certain clinical milestones in the development of OpRegen<sup>®</sup> and Renevia<sup>®</sup>. Stock-based compensation expense for these performance-based RSUs is recognized when it is probable that the respective milestone will be achieved, as determined by BioTime's Board of Directors. On October 4, 2018, BioTime's Board of Directors determined that BioTime had achieved the AgeX Distribution performance condition and as a result 25%, or 123,250, of the RSUs granted in May and August 2018 vested. On December 18, 2018, BioTime's Board of Directors determined that BioTime had achieved other milestones related to the RSUs and as a result an additional 50%, or 246,500, of the RSUs granted in May and August 2018 vested. The remaining 25%, or 123,250 RSUs, expired unvested on December 31, 2018.

On September 17, 2018, BioTime granted BioTime’s new President and Chief Executive Officer, Brian M. Culley, two RSU awards under the 2012 Plan: (1) an award of 200,000 restricted stock units (“RSU Award No. 1”) and (2) an award of 100,000 restricted stock units (“RSU Award No. 2” and together with RSU Award No. 1, the “RSU Awards”). Subject to Mr. Culley’s continued service with BioTime, 25% of the shares subject to RSU Award No. 1 will vest on the first anniversary of the date of grant, and the balance of the shares subject to RSU Award No. 1 will vest in 12 equal quarterly installments at the end of each quarter thereafter. RSU Award No. 2 vested in full on January 1, 2019.

<sup>(4)</sup>On September 17, 2018 (the “Start Date”), Brian M. Culley became President and Chief Executive Officer of BioTime. In connection with Mr. Culley’s employment, BioTime granted Mr. Culley an inducement option to purchase 1,500,000 of BioTime’s common shares (the “Culley Option”). The exercise price of the Culley Option is \$2.31 per share, which was the closing stock price on September 17, 2018. This grant was made outside of the 2012 Plan and was approved by the independent members of the Board of Directors. Subject to Mr. Culley’s continued service with BioTime on the applicable vesting date, the Culley Option will vest and become exercisable with respect to 25% of the shares on the first anniversary of the Start Date, and the balance of the Culley Option will vest and become exercisable in 36 equal monthly installments thereafter.

<sup>(5)</sup> Reflects the equitable adjustment to the exercise prices and number of outstanding stock options, and to restricted stock units, necessary to maintain the intrinsic value of those awards immediately prior to and following the AgeX Distribution.

In connection with the vested RSUs during the year ended December 31, 2018, BioTime paid \$0.2 million in minimum employee withholding taxes in exchange for 134,000 vested shares of BioTime common stock issuable to the employees and immediately retired those shares. For the year ended December 31, 2018, BioTime recorded a noncash stock-based compensation expense of \$1.2 million, which includes \$1.0 million related to the performance-based awards discussed above, in connection with the vested RSUs, included in consolidated stock-based compensation expense.

As of December 31, 2018, additional information regarding options outstanding under the 2012 Plan and options outstanding outside of the 2012 Plan, is as follows (in thousands except exercise prices and weighted average exercise price):

Range of Exercise Prices <sup>(1)</sup>	Options Outstanding		Options Exercisable	
	Number	Weighted Average Remaining	Number	Weighted Average
	Outstanding	Average	Exercisable	Average

		<b>Contractual</b>	<b>Exercise</b>		<b>Exercise</b>
		<b>Life (years)</b>	<b>Price<sup>(1)</sup></b>		<b>Price<sup>(1)</sup></b>
\$1.67 - \$3.20	12,803	7.12	\$ 2.38	6,810	\$ 2.56
\$3.25 - \$4.01	1,064	2.33	\$ 3.46	1,046	\$ 3.42
\$2.04 - \$6.94	13,867	6.75	\$ 2.44	7,856	\$ 2.67

<sup>(1)</sup> After adjustment to the applicable exercise prices, number of outstanding and exercisable stock options necessary to maintain the intrinsic value of those awards immediately prior to and following the AgeX Distribution.

## 14. Income Taxes

### *U.S. Federal Income Tax Reform*

On December 22, 2017, in response to the enactment of the 2017 Tax Act (see Note 2), the SEC staff issued SAB 118 that allows companies to record provisional amounts during a measurement period not to extend beyond one year from the enactment date. The repatriation tax is based primarily on LifeMap Sciences Ltd, an Israeli subsidiary of LifeMap Sciences, accumulated foreign earnings and profits that BioTime previously excluded from U.S. income taxes. As a result, LifeMap Sciences included \$227,000 in foreign earnings in federal income for the year ended December 31, 2017. The federal taxable income was offset by the LifeMap Sciences' net operating loss carryforwards resulting in no federal income tax due.

In addition, for the year ended December 31, 2017, BioTime remeasured certain deferred tax assets and liabilities based on the enacted tax rate at which they are expected to reverse in the future. The estimated tax effected amount related to the remeasurement of these balances was a reduction of BioTime's net deferred tax assets by \$8.9 million with a corresponding decrease in the valuation allowance by the same amount, recognized as of December 31, 2017, discussed below. BioTime applied the guidance in SAB 118 when accounting for the enactment-date effects of the 2017 Tax Act for the years ended December 31, 2018 and 2017. As of December 31, 2018, BioTime completed its accounting for all the enactment-date income tax effects of the 2017 Tax Act.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. As of December 31, 2017, the federal portion of the deferred tax assets and liabilities for 2017 were re-rated from 34% to 21% pursuant to the 2017 Tax Act.

The primary components of the deferred tax assets and liabilities at December 31, 2018 and 2017 were as follows (in thousands):



Deferred tax assets/(liabilities):	2018	2017
Net operating loss carryforwards	\$37,761	\$55,608
Research and development and other credits	5,288	6,548
Patents and licenses	1,080	910
Equity method investments and marketable securities at fair value	(7,848)	(23,946)
Stock options	2,062	713
Other, net	174	812
Total	38,517	40,645
Valuation allowance	(38,517)	(40,645)
Net deferred tax assets	\$-	\$-

A valuation allowance is provided when it is more likely than not that all or some portion of the deferred tax assets will not be realized. BioTime established a full valuation allowance for all periods presented due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets, including foreign net operating losses generated by its subsidiaries.

Income taxes differed from the amounts computed by applying the indicated current U.S. federal income tax rate to pretax losses from operations as a result of the following:

	Year Ended	
	December 31,	
	2018	2017
Computed tax benefit at federal statutory rate	21%	34%
Research and development and other credits	1%	2%
Re-rate of federal net deferred tax assets	-	(38%)
Permanent differences	(3%)	(8%)
Change in valuation allowance	4%	(32%)
Establish deferred tax liability for AgeX/OncoCyte shares at deconsolidation	8%	17%
Deconsolidation of AgeX and subsidiaries net deferred tax assets	(28%)	-
State tax benefit, net of effect on federal income taxes	-	27%
Foreign rate differential	(2%)	(2%)
Income tax benefit	1%	-%

BioTime recorded a federal current income tax benefit of \$0.3 million for the year ended December 31, 2018 due to intraperiod allocation discussed below (see Note 2). No income tax provision or benefit was recorded for the year ended December 31, 2017 due to a full valuation allowance on the deferred tax assets.

As of December 31, 2018, BioTime has gross net operating loss carryforwards of approximately \$93.8 million for federal purposes. As a result of the deconsolidation of AgeX on August 30, 2018 (Notes 3 and 4), AgeX and its subsidiaries will not be included in the federal consolidated and state combined tax returns of BioTime after that date.



Accordingly, AgeX and its subsidiaries will file their own separate federal consolidated and state combined tax returns. In addition, AgeX and its subsidiaries will keep their separate tax attributes, consisting primarily of net operating loss carryforwards and research and development credits which will not be available to offset the taxable income of BioTime and not be included in the schedule of deferred tax assets and liabilities at December 31, 2018. As of December 31, 2018, BioTime's foreign subsidiaries have net operating loss carryforwards of approximately \$72.9 million which carryforward indefinitely.

As of December 31, 2018, BioTime has net operating losses of \$43.1 million for state tax purposes. Historically, the activities of OncoCyte, AgeX, ReCyte, LifeMap Sciences and OncoCyte have been included in the combined California tax return with BioTime. As a result of the OncoCyte Deconsolidation on February 17, 2017, (see Note 5), OncoCyte will file a separate California return for tax years 2018 and 2017. As a result of the AgeX Deconsolidation on August 30, 2018, AgeX and its subsidiaries, ReCyte, LifeMap Sciences Inc. and LifeMap Sciences Ltd (the "AgeX Group") will file a separate California return after that date. Accordingly, the California net operating loss carryforwards and research and development credits attributable to the AgeX Group will not be available to BioTime and not included in the schedule of deferred tax assets and liabilities at December 31, 2018.

Federal net operating losses generated on or prior to December 31, 2017, expire in varying amounts between 2028 and 2037, while federal net operating losses generated after December 31, 2017, carryforward indefinitely. The state net operating losses expire in varying amounts between 2030 and 2037.

As of December 31, 2018, BioTime has research tax credit carryforwards for federal and state tax purposes of \$2.5 million and \$2.8 million, respectively. As noted above, as a result of the AgeX Deconsolidation, these tax credits reflect the amounts for BioTime and OrthoCyte as of December 31, 2018. For federal purposes, the credits generated each year have a carryforward period of 20 years. The federal tax credits expire in varying amounts between 2019 and 2038, while the state tax credits have no expiration period.

On March 23, 2018, Ascendance was acquired by a third party in a merger through which AgeX received approximately \$3.2 million in cash for its shares of Ascendance common stock. For financial reporting purposes, AgeX recognized a \$3.2 million gain as a sale of its equity method investment in Ascendance. The sale was a taxable transaction to AgeX generating a taxable gain of approximately \$2.2 million. BioTime has sufficient net operating losses to offset the entire gain resulting in no income taxes due.

The Juvenescence Transaction discussed in Note 3 was a taxable event for BioTime that resulted in a gross taxable gain of approximately \$29.4 million, which BioTime expects to be fully offset with available net operating losses (“NOL”) and NOL carryforwards, resulting in no net income taxes due. Although the AgeX Deconsolidation on August 30, 2018 was not a taxable transaction to BioTime and did not result in a current tax payment obligation, the unrealized financial reporting gain (see Note 4) on the AgeX Deconsolidation generated a deferred tax liability in accordance with ASC 740, primarily representing BioTime’s difference between book and tax basis of AgeX common stock on the AgeX Deconsolidation date. BioTime expects this deferred tax liability to be fully offset by a corresponding release of BioTime’s valuation allowance on deferred tax assets, resulting in no income tax provision or benefit from the AgeX Deconsolidation. The deferred tax liabilities on BioTime’s investments in OncoCyte, Asterias and AgeX are considered to be sources of taxable income as prescribed by ASC 740-10-30-17 that will more likely than not result in the realization of its deferred tax assets to the extent of those deferred tax liabilities, thereby reducing the need for a valuation allowance.

The distribution of AgeX shares of common stock to BioTime shareholders (see Note 4) on November 28, 2018 was a taxable event for BioTime that resulted in a gross taxable gain of approximately \$26.4 million, which BioTime expects to be fully offset with available net operating losses, resulting in no income taxes due.

Although the OncoCyte Deconsolidation on February 17, 2017 was not a taxable transaction to BioTime and did not result in a tax payment obligation, the \$71.7 million unrealized gain on the OncoCyte Deconsolidation generated a deferred tax liability that was fully offset by BioTime’s net operating losses. Subsequent to the OncoCyte Deconsolidation, an unrealized loss of \$2.9 million was recorded on the OncoCyte shares during the year ended December 31, 2017, which was fully offset by a corresponding increase in BioTime’s valuation allowance. An unrealized loss of \$48.0 million was recorded on the OncoCyte shares during the year ended December 31, 2018, which was fully offset by a corresponding increase in BioTime’s valuation allowance.

Similarly, the Asterias Deconsolidation on May 13, 2016 was not a taxable transaction to BioTime and did not result in a tax payment obligation, the \$49.0 million gain on the Asterias Deconsolidation generated a deferred tax liability that was fully offset by BioTime’s 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. Unrealized losses of \$35.4 million and \$51.1 million were recorded on the Asterias shares during the years ended December 31, 2018 and 2017, respectively, which were fully offset by a corresponding increase in BioTime’s valuation allowance.

In connection with the deconsolidation of OncoCyte and Asterias (see Notes 5, 6 and 7), the market value of the respective shares BioTime holds creates a deferred tax liability to BioTime based on the closing price of the security, less the tax basis of the security BioTime has in such shares. The deferred tax liability generated by OncoCyte and Asterias shares that BioTime holds as of December 31, 2018, is a source of future taxable income to BioTime, as prescribed by ASC 740-10-30-17, that will more likely than not result in the realization of its deferred tax assets to the extent of those deferred tax liabilities. This deferred tax liability is determined based on the closing price of those

securities as of December 31, 2018.

On June 6, 2017, BioTime and LifeMap Sciences entered into a Debt Conversion Agreement whereby BioTime acquired additional stock in LifeMap Sciences (see Note 12) and other assets, including intellectual property in exchange for intercompany indebtedness of approximately \$8.7 million owed to BioTime. This transaction had no financial reporting impact, except for transactions between noncontrolling interests of LifeMap Sciences discussed in Note 12. BioTime and LifeMap Sciences recorded the tax effect of the transactions in equity instead of the tax provision in accordance with ASC 740-20-45-11(g), which requires that the tax effects of all changes in tax bases of assets and liabilities caused by transactions among or with shareholders be included in equity. In connection with the June 2017 transactions, LifeMap Sciences utilized approximately \$3.3 million in net operating loss carryforwards with a corresponding release of the valuation allowance recorded through equity in accordance with ASC 740-20-45-11(g).

For income tax purposes, the purchase by BioTime of LifeMap Sciences' intellectual property and other assets resulted in a taxable gain to LifeMap Sciences of \$3.7 million for the year ended December 31, 2017. Although LifeMap Sciences had sufficient current year operating losses and regular net operating loss carryforwards to offset the entire gain, it incurred a federal alternative minimum tax payable of \$22,000 as of December 31, 2017. As previously noted under the 2017 Tax Act, corporations are no longer subject to the AMT, effective for taxable years beginning after December 31, 2017. To the extent a company has an AMT credit from a prior year, the company can carry the credit forward to offset regular tax. To the extent the company does not have a federal tax liability, a portion of the AMT credit is refundable each year starting in 2018, with any remaining balance fully refundable in 2021. As LifeMap Sciences will ultimately receive a full refund of the current AMT payable, fully offsetting the current provision, there is no tax provision or benefit recorded for the year ended December 31, 2017.

For the year ended December 31, 2018, because BioTime experienced a loss from continuing operations and generated other comprehensive income attributable to foreign currency translation adjustments, BioTime allocated income tax expense against the component of foreign currency translation adjustment in 2018 using a 21% tax rate. Income tax benefit related to continuing operations for the year ended December 31, 2018 includes a tax benefit of \$0.3 million due to the required intraperiod tax allocation (see Note 2). Conversely, other comprehensive income attributable to foreign currency translation adjustments for the year ended December 31, 2018 is net of an income tax expense of \$0.3 million.

#### *Other Income Tax Matters*

Internal Revenue Code Section 382 places a limitation (“Section 382 Limitation”) on the amount of taxable income that can be offset by NOL carryforwards after a change in control (generally greater than 50% change in ownership within a three-year period) of a loss corporation. California has similar rules. Generally, after a change in control, a loss corporation cannot deduct NOL carryforwards in excess of the Section 382 Limitation. Due to these “change in ownership” provisions, utilization of the NOL and tax credit carryforwards may be subject to an annual limitation regarding their utilization against taxable income in future periods.

BioTime files a U.S. federal income tax return as well as various state and foreign income tax returns. In general, BioTime is no longer subject to tax examination by major taxing authorities for years before 2014. Although the statute is closed for purposes of assessing additional income and tax in these years, the taxing authorities may still make adjustments to the NOL and credit carryforwards used in open years. Therefore, the statute should be considered open as it relates to the NOL and credit carryforwards used in open years.

BioTime may be subject to potential examination by U.S. federal, U.S. states or foreign jurisdiction authorities in the areas of income taxes. These potential examinations may include questioning the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with U.S. federal, U.S. state and foreign tax laws. BioTime’s management does not expect that the total amount of unrecognized tax benefits will materially change over the next twelve months.

BioTime’s practice is to recognize interest and penalties related to income tax matters in tax expense. As of December 31, 2018 and 2017, BioTime has no accrued interest and penalties.

## **15. Commitments and Contingencies**

*Alameda Lease*

In December 2015, BioTime entered into a lease for approximately 30,795 square feet of rentable space in two buildings located in an office park in Alameda, California (the “Alameda Lease”). The term of the Alameda Lease is seven years and BioTime has an option to renew the term for an additional five years. The term of the Alameda Lease commenced effective February 1, 2016 and expires on January 31, 2023, unless the renewal option is exercised.

Base rent under the Alameda Lease beginning on February 1, 2019 is \$70,521 per month and will increase by approximately 3% annually on every February 1 thereafter during the lease term. The lease payments allocated to the lease liability for leasehold improvements reimbursed by the landlord are amortized as debt service on that liability using the effective interest method over the lease term.

In addition to base rent, BioTime will pay a pro rata portion of increases in certain expenses, including real property taxes, utilities (to the extent not separately metered to the leased space) and the landlord’s operating expenses, over the amounts of those expenses incurred by the landlord. As security for the performance of its obligations under the Alameda Lease, BioTime provided the landlord with a security deposit of approximately \$424,000, which was reduced to \$78,000 on January 24, 2019 in accordance with the terms of the lease. The security deposit amount is considered restricted cash (see Note 2).

*New York Leased Office Space*

BioTime currently pays \$5,050 per month for the use of approximately 900 square feet of office space in New York City, which is made available to BioTime for use in conducting meetings and other business affairs, on a month-by-month basis, by one of its directors at an amount that approximates his cost.

*Cell Cure Leases*

Cell Cure has leased 728.5 square meters (approximately 7,842 square feet) of office and laboratory space in Jerusalem, Israel under a lease that expires December 31, 2020, with two additional options to extend the lease for 5 years each. Base monthly rent is NIS 37,882 (approximately US \$11,000 per month using the December 31, 2018 exchange rate).

On January 28, 2018, Cell Cure entered into another lease agreement for an additional 934 square meters (approximately 10,054 square feet) of office space in the same facility in Jerusalem, Israel under a lease that expires on December 31, 2025, with two additional options to extend the lease for 5 years each (the “January 2018 Lease”). The January 2018 Lease commenced on April 1, 2018 and included a leasehold improvement construction allowance of up to NIS 4,000,000 (approximately up to \$1.1 million using the December 31, 2018 exchange rate) from the landlord.

Cell Cure is considered the owner of the tenant improvements under construction under ASC 840-40-55 as Cell Cure, among other things, has the primary obligation to pay for construction costs and Cell Cure will retain exclusive use of the leased facilities for its office, research and cGMP manufacturing facility requirements after construction is completed. In accordance with this guidance, amounts expended by Cell Cure for construction is reported as construction in progress, and the proceeds received from the landlord, if any, are reported as a lease liability. As of December 31, 2018, approximately \$0.8 million in reimbursable amounts due to Cell Cure but not yet paid by the landlord are recorded as a landlord receivable with a corresponding increase to the lease liability since Cell Cure has contractually earned the right to receive that payment. Upon the property being placed in service, Cell Cure will depreciate the property (see Note 8) and the lease payments attributable to the lease liability will be accounted for as debt service payments using the effective interest method over a ten year amortization period beginning on October 1, 2018.

As of December 31, 2018, approximately \$1.1 million under the January 2018 Lease was incurred and recorded as leasehold improvement construction in progress (see Note 8), with a corresponding amount included in long term lease liability representing the full amount utilized from the landlord’s leasehold improvement construction allowance. Amounts incurred above the construction allowance are paid by Cell Cure. The leasehold improvements were substantially completed in December 2018 and the assets placed in service in January 2019. Combined base rent and construction allowance payments for the January 2018 Lease are NIS 93,827 per month (approximately \$26,000 per month) beginning on October 1, 2018.

In December 2018, Cell Cure made a \$388,000 deposit required under the January 2018 Lease, which amount is included in deposits and other long-term assets on the consolidated balance sheet as of December 31, 2018, to be held as restricted cash during the term of the January 2018 Lease.

In addition to base rents, 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.

*Annual Rent Expense and Future Minimum Lease Payments*

Rent expense totaled \$1.2 million and \$1.1 million for the years ended December 31, 2018 and 2017, respectively, included in the consolidated statements of operations.

Future minimum annual lease payments under the various operating leases, including the Alameda Lease and the landlord lease liability, Cell Cure leases noted above, and capital leases, for the years ending after December 31, 2018 are as follows (in thousands):

Year Ending December 31,	<b>Minimum Operating Lease Payments</b>	<b>Capital Lease Payments</b>
2019	\$ 1,421	\$ 36
2020	1,339	36
2021	1,245	36
2022	1,251	36
2023	393	15
Thereafter	1,015	-
Total minimum lease payments	\$ 6,664	\$ 159
Less amounts representing interest		(31)
Present value of net minimum lease payments		\$ 128

*Litigation – General*

BioTime will be subject to various claims and contingencies in the ordinary course of its business, including those related to litigation, business transactions, employee-related matters, and others. When BioTime is aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, BioTime will record a liability for the loss. If the loss is not probable or the amount of the loss cannot be reasonably estimated, BioTime discloses the claim if the likelihood of a potential loss is reasonably possible and the amount involved could be material (see Note 19).

*Employment Contracts*

BioTime has entered into employment agreements with certain executive officers. Under the provisions of the agreements, BioTime may be required to incur severance obligations for matters relating to changes in control, as defined in the agreements, and involuntary terminations.

*Indemnification*

In the normal course of business, BioTime may provide indemnifications of varying scope under BioTime's agreements with other companies or consultants, typically BioTime's clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, BioTime will generally agree to indemnify, hold harmless, and reimburse the indemnified parties for losses and expenses suffered or incurred by the indemnified parties arising from claims of third parties in connection with the use or testing of BioTime's products and services. Indemnification provisions could also cover third party infringement claims with respect to patent rights, copyrights, or other intellectual property pertaining to BioTime products and services. The term of these indemnification agreements will generally continue in effect after the termination or expiration of the particular research, development, services, or license agreement to which they relate. The potential future payments BioTime could be required to make under these indemnification agreements will generally not be subject to any specified maximum amount. Historically, BioTime has not been subject to any claims or demands for indemnification. BioTime also maintains various liability insurance policies that limit BioTime's financial exposure. As a result, BioTime believes the fair value of these indemnification agreements is minimal. Accordingly, BioTime has not recorded any liabilities for these agreements as of December 31, 2018 and 2017.

*Second Amended and Restated License Agreement*



On June 15, 2017, Cell Cure entered into a Second Amended and Restated License Agreement (the “License Agreement”) with Hadasit Medical Research Services and Development Ltd. (“Hadasit”), the commercial arm and a wholly-owned subsidiary of Hadassah Medical Organization. Pursuant to the License Agreement, Hadasit granted Cell Cure an exclusive, worldwide, royalty bearing license (with the right to grant sublicenses) in its intellectual property portfolio of materials and technology related to human stem cell derived photoreceptor cells and retinal pigment epithelial cells (the “Licensed IP”), to use, commercialize and exploit any part thereof, in any manner whatsoever in the fields of the development and exploitation of (i) human stem cell derived photoreceptor cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders, and (ii) human stem cell derived retinal pigment epithelial cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders.

As consideration for the Licensed IP, Cell Cure will pay a small one-time lump sum payment, a royalty in the mid-single digits of net sales from sales of Licensed IP by any invoicing entity, and a royalty of 21.5% of sublicensing receipts. In addition, Cell Cure will pay Hadasit an annual minimal non-refundable royalty, which will become due and payable the first January 1 following the completion of services to Cell Cure by a research laboratory.

Cell Cure will pay Hadasit non-refundable milestone payments upon the recruitment of the first patient for the first Phase IIB clinical trial, upon the enrollment of the first patient in the first Phase III clinical trials, upon delivery of the report for the first Phase III clinical trials, upon the receipt of an NDA or marketing approval in the European Union, whichever is the first to occur, and upon the first commercial sale in the United States or European Union, whichever is the first to occur. Such milestones, in the aggregate, may be up to \$3.5 million. As of December 31, 2018, Cell Cure had not accrued any milestone payments under the License Agreement.

The License Agreement terminates upon the expiration of Cell Cure’s obligation to pay royalties for all licensed products, unless earlier terminated. In addition to customary termination rights of both parties, Hadasit may terminate the License Agreement if Cell Cure fails to continue the clinical development of the Licensed IP or fails to take actions to commercialize or sell the Licensed IP over any consecutive 12 month period. The License Agreement also contains mutual confidentiality obligations of Cell Cure and Hadasit, and indemnification obligations of Cell Cure.

### *Royalty obligations and license fees*

BioTime and its subsidiaries or affiliates are parties to certain licensing agreements with research institutions, universities and other parties for the rights to use those licenses and other intellectual property in conducting research and development activities. These licensing agreements provide for the payment of royalties by BioTime or the applicable party to the agreement on future product sales, if any. In addition, in order to maintain these licenses and other rights during the product development, BioTime or the applicable party to the contract must comply with various conditions including the payment of patent related costs and annual minimum maintenance fees. Annual minimum maintenance fees are approximately \$135,000 to \$150,000 per year. The research and development risk for these products is significant. License fees and related expenses under these agreements were \$133,000 and \$221,000 for the years ended December 31, 2018 and 2017, respectively.

### *Grants*

Under the terms of the grant agreement between Cell Cure and Israel Innovation Authority (“IIA”) (formerly the Office of the Chief Scientist of Israel) of the Ministry of Economy and Industry, for the development of *OpRegen*<sup>®</sup>, 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. Cell Cure’s research and product development activities under the grant are subject to substantial risks and uncertainties and performed on a best efforts basis. As a result, Cell Cure is not required to make any payments under the grant agreement unless it successfully commercializes *OpRegen*<sup>®</sup>. Accordingly, pursuant to ASC 730-20, the Cell Cure grant is considered a contract to perform research and development services for others and grant revenue is recognized as the related research and development expenses are incurred (see Note 2).

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.

## **16. Segment Information**

BioTime’s executive management team, as a group, represents the entity’s chief operating decision makers. BioTime’s executive management team views BioTime’s operations as one segment that includes, the research and development of therapeutic products for retinal, orthopedics, oncology, and neurological diseases and disorders, blood and vascular system diseases and disorders, blood plasma volume expansion, diagnostic products for the early detection of cancer, and hydrogel products that may be used in surgery, and products for pluripotent cell technologies. As a result, the financial information disclosed materially represents all of the financial information related to BioTime’s sole operating segment.

**17. Enterprise-Wide Disclosures***Geographic Area Information*

The following table presents consolidated revenues, including license fees, royalties, grant income, and other revenues, disaggregated by geography, based on the billing addresses of customers, or in the case of grant revenues based on where the governmental entities that fund the grant are located (in thousands).

<b>Geographic Area</b>	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017 (1)</b>
United States	\$1,804	\$1,651
Foreign (2)	3,184	1,807
Total revenues	\$4,988	\$3,458

(1) Amounts recognized prior to adoption of Topic 606 have not been adjusted under the Topic 606 modified retrospective transition method.

(2) Foreign revenues are primarily generated from grants in Israel.

The composition of BioTime's long-lived assets, consisting of plant and equipment, net, between those in the United States and in foreign countries, as of December 31, 2018 and 2017, is set forth below (in thousands):

	December 31,	
	<b>2018</b>	2017
	(1)	
Domestic	\$2,038	\$2,746
Foreign <sup>(2)</sup>	3,797	2,787
Total	\$5,835	\$5,533

(1) Reflects the effect of the AgeX Deconsolidation.

(2) Assets in foreign countries principally include laboratory equipment and leasehold improvements in Israel.

### *Major Sources of Revenues*

The following table presents BioTime's consolidated revenues disaggregated by source (in thousands).

	Year Ended	
	December 31,	
	<b>2018</b>	<b>2017</b>
		(1)
<b>REVENUES:</b>		
Grant revenue	\$3,572	\$1,666
Royalties from product sales and license fees	392	389
Subscription and advertisement revenues <sup>(2)</sup>	691	1,395
Sale of research products and services	333	8
Total revenues	\$4,988	\$3,458

(1) Amounts recognized prior to adoption of Topic 606 have not been adjusted under the Topic 606 modified retrospective transition method.

These revenues were generated by LifeMap Sciences, a subsidiary of AgeX. The revenues shown for 2018 are for (2) the period January 1, 2018 through August 29, 2018. As a result of the AgeX Deconsolidation on August 30, 2018, BioTime does not expect to recognize this type of revenue in subsequent accounting periods.

The following table shows BioTime's major sources of revenues, as a percentage of total revenues, that were recognized during the years ended December 31, 2018, 2017, and 2016:

Sources of Revenues	Year Ended	
	2018	2017

Edgar Filing: BIOTIME INC - Form 10-K

NIH grant income <sup>(1)</sup>	21.2%	5.0%
IIA (formerly OCS) grant income (Cell Cure, Israel)	50.4%	43.2%
Subscriptions, advertising, licensing and other (various customers) <sup>(2)</sup>	20.5%	49.4%
Sale of research products	4.2%	-%
Other	3.7%	2.4%

(1) Reflects income from grants to BioTime from the National Institutes of Health (NIH).

(2) For 2018 and 2017, one individual customer represents greater than 5% of total revenues.

Between January 1, 2018 through August 29, 2018, LifeMap Sciences received \$0.7 million and recognized \$0.5 million (net of \$0.2 million in royalty and commission fees included in cost of sales) in net subscription and advertisement revenues from LifeMap Sciences' online database business primarily related to its *GeneCard*<sup>®</sup> database. During 2017, LifeMap Sciences received \$1.4 million and recognized \$1.2 million (net of \$168,000 in royalty and commission fees included in cost of sales) in net subscription and advertisement revenues from LifeMap Sciences' online database business primarily related to its *GeneCard*<sup>®</sup> database.

**18. Selected Quarterly Financial Information (UNAUDITED, in thousands, except per share data)**

BioTime has derived this data from the unaudited consolidated interim financial statements that, in BioTime' s opinion, have been prepared on substantially the same basis as the audited consolidated financial statements contained herein and include all normal recurring adjustments necessary for a fair presentation of the financial information for the periods presented. These unaudited consolidated quarterly results should be read in conjunction with the consolidated financial statements and notes thereto included herein. The consolidated operating results in any quarter are not necessarily indicative of the consolidated results that may be expected for any future period.

Year Ended December 31, 2018	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues, net	\$701	\$2,547	\$982	\$758
Operating expenses	12,779	11,585	11,304	10,813
Loss from operations	(12,187)	(9,144)	(10,357)	(10,107)
Net income (loss) attributable to BioTime	(63,548)	(4,215)	66,725	(44,952)
Basic net income (loss) per share	\$(0.50)	\$(0.03)	\$0.53	\$(0.36)
Year Ended December 31, 2017				
Revenues, net	\$333	\$376	\$1,636	\$945
Operating expenses	11,595	10,694	11,149	10,508
Loss from operations	(11,262)	(8,564)	(9,513)	(9,563)
Net income (loss) attributable to BioTime	49,288	(11,651)	14,321	(71,934)
Basic net income (loss) per share	\$0.46	\$(0.11)	\$0.12	\$(0.58)

Quarterly and year-to-date computations of net income (loss) per share amounts are calculated using the respective period weighted average shares outstanding. Therefore, the sum of the per share amounts for the quarters may not agree with the per share amounts for the year.

## 19. Subsequent Events

### *Research and Option Agreement*

On January 5, 2019, BioTime and Orbit Biomedical Limited (“Orbit”) entered into a Research and Option Agreement (the “Orbit Agreement”) for an exclusive partnership to assess Orbit’s vitrectomy-free subretinal injection device as a means of delivering OpRegen in the ongoing Phase I/IIa study. The term of the Orbit Agreement is for one year unless certain research activities and related data specified in the Orbit Agreement is obtained sooner. The access fees payable by BioTime to Orbit for its technology and the injection device are \$2.5 million in the aggregate, of which \$1.25 million was paid in January 2019 upon execution of the Orbit Agreement and the remaining \$1.25 million payment is due on the earlier of (i) six months from the Orbit Agreement date or, (ii) upon completion of certain collaborative research activities using the Orbit technology for the OpRegen clinical trial, as specified in the Orbit Agreement. In addition to the access fees, BioTime will pay Orbit for costs of consumables, training services, travel costs and other out of pocket expenses incurred by Orbit for performing services under the Orbit Agreement. BioTime will have exclusive rights to the Orbit technology and its injection device for the treatment of dry-AMD during the term of the Orbit Agreement and may extend the term for an additional three months by paying Orbit a cash fee of \$500,000.

*Option Grants*

In January and February 2019, BioTime granted stock options to purchase 1.7 million common shares with exercise prices ranging from \$1.08 per share to \$1.14 per share to its employees, including to its new Chief Financial Officer hired in January 2019, under the 2012 Plan. These grants are subject to the customary vesting terms and conditions in accordance with the 2012 Plan.

*Payment of Receivable from OncoCyte*

On February 15, 2019, OncoCyte paid the \$2.1 million in shared services due to BioTime (see Note 11) as of December 31, 2018.

*Asterias Merger*

On November 7, 2018, BioTime, Asterias and Patrick Merger Sub, Inc., a wholly owned subsidiary of BioTime (“Merger Sub”), entered into an Agreement and Plan of Merger (the “Merger Agreement”) whereby BioTime will acquire all of the outstanding common stock of Asterias in a stock-for-stock transaction of 0.71 shares of BioTime common shares for every share of Asterias common stock (the “Asterias Merger”).

On February 19, 2019, a putative shareholder class action lawsuit was filed (captioned *Lampe v. Asterias Biotherapeutics, Inc. et al.*, Case No. RG19007391) in the Superior Court of the State of California, County of Alameda challenging the Asterias Merger. The complaint names BioTime, Asterias, Patrick Merger Sub, Inc., the Asterias board of directors, one member of BioTime's board of directors, and certain stockholders of both BioTime and Asterias. The action was brought by a purported stockholder of Asterias, on behalf of a putative class of Asterias stockholders, and asserts breach of fiduciary duty and aiding and abetting claims under Delaware law. The complaint alleges, among other things, that the process leading up to the Asterias Merger was conflicted and inadequate, and that the proxy statement filed by Asterias with the Securities and Exchange Commission omits certain material information, which allegedly renders the information disclosed materially misleading. The complaint seeks, among other things, to enjoin the Asterias Merger, or in the event the Asterias Merger is consummated, to recover monetary damages.

BioTime believes that the allegations lack merit and intends to vigorously defend all claims asserted. It is impossible at this time to assess whether the outcome of this proceeding will have a material adverse effect on BioTime's consolidated results of operations, cash flows or financial position. Therefore, in accordance with ASC 450, *Contingencies*, BioTime has not recorded any accrual for a contingent liability associated with this legal proceeding based on its belief that a liability, while possible, is not probable nor estimable, and any range of potential contingent liability amounts cannot be reasonably estimated at this time. BioTime records legal expenses as incurred.

On March 7, 2019, the shareholders of each of BioTime and Asterias approved the Merger Agreement. As discussed in Note 7, prior to the consummation of the Merger Agreement, BioTime owned approximately 39% of Asterias' issued and outstanding common stock and accounts for Asterias as an equity method investment.

On March 8, 2019, the Asterias merger closed and the Merger Sub merged with and into Asterias with Asterias surviving the Asterias Merger as a wholly-owned subsidiary of BioTime. Pursuant to the terms of the Merger Agreement, at the closing of the merger on March 8, 2019, Asterias became a wholly owned subsidiary of BioTime and the previous stockholders of Asterias (other than BioTime) received 0.71 shares of BioTime common share for every share of Asterias common stock (the "Merger Consideration"). In the Merger Consideration, BioTime issued 24,729,516 number of shares of common stock, which included 91,703 shares issued for all Asterias restricted stock units that immediately vested in connection with the Asterias Merger, for aggregate Merger Consideration of \$32.4 million. BioTime also assumed 1,997,342 of Asterias warrants and the Asterias option pool which includes 5,189,520 shares.

The Asterias Merger will be accounted for using the acquisition method of accounting in accordance with Accounting Standards Codification Topic 805 ("ASC 805"), *Business Combinations*, which requires, among other things, that the assets and liabilities assumed be recognized at their fair values as of the acquisition date. The acquisition related disclosures required by ASC 805 cannot be made as the initial accounting for the Asterias Merger is incomplete. Key financial data such as the determination of the fair value of the assets acquired and liabilities assumed is not yet available.





**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Securities Exchange Act of 1934 ("Exchange Act"). Our management, including our principal executive officer and our principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of the end of our fourth quarter. Following this review and evaluation, management collectively determined that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms; and (ii) is accumulated and communicated to management, including our chief executive officer and our chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during the period covered by this Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Management's Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f), is a process designed by, or under the supervision of, our principal executive officer, our principal operations officer, and our principal financial officer, and effected by our Board of Directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. The scope of management's assessment of the effectiveness of internal control over financial reporting includes our consolidated subsidiaries.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018, based on criteria established in the 2013 Internal Control - Integrated Framework issued by COSO. Based on this assessment, management believes that, as of that date, our internal control over financial reporting was effective.

This Report includes an attestation report of our independent registered public accounting firm regarding internal control over financial reporting for the year ended December 31, 2018. The attestation is included with the accounting firm's report on our audited consolidated financial statements.

## **ITEM 9B. OTHER INFORMATION**

Not applicable

## **PART III**

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE**

The name, age, and background of each of our directors are contained under the caption “Election of Directors” in our Proxy Statement for our 2019 Annual Meeting of Shareholders and are incorporated herein by reference. Information about our executive officers, committees of the Board of Directors, and compensation of directors is reported under the caption “Corporate Governance” in our Proxy Statement for our 2019 Annual Meeting of Shareholders and is incorporated herein by reference.

We have a written Code of Ethics that applies to our principal executive officer, our principal financial officer and accounting officer, our other executive officers, and our directors. The purpose of the Code of Ethics is to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with or submit to the Securities and Exchange Commission and in our other public communications; (iii) compliance with applicable governmental rules and regulations; (iv) prompt internal reporting of violations of the Code of Ethics to an appropriate person or persons identified in the Code; and (v) accountability for adherence to the Code. A copy of our Code of Ethics has been posted on our internet website and can be found at [www.biotimeinc.com](http://www.biotimeinc.com). If we amend or waive a provision of our Code of Ethics that applies to our chief executive officer or chief financial officer, we will post the amended Code of Ethics or information about the waiver on our internet website.

Information about our compliance with Section 16(a) of the Securities Exchange Act of 1934 is reported under the caption “Compliance with Section 16(a) of the Securities Exchange Act of 1934” in our Proxy Statement for our 2019 Annual Meeting of Shareholders and is incorporated herein by reference.

### **ITEM 11. EXECUTIVE COMPENSATION**

Information on compensation of our executive officers is reported under the caption “Executive Compensation” in our Proxy Statement for our 2019 Annual Meeting of Shareholders and is incorporated herein by reference.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT, AND RELATED STOCKHOLDER MATTERS**

Information on the number of common shares of BioTime beneficially owned by each shareholder known by us to be the beneficial owner of 5% or more of our common shares, and by each director and named executive officer, and by all directors and named executive officers as a group, is contained under the caption “Principal Shareholders” and “Equity Compensation Plan Information” in our Proxy Statement for our 2019 Annual Meeting of Shareholders, and is incorporated herein by reference.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Information about transactions with related persons; review, and approval or ratification of transactions with related persons; and director independence is reported under the captions “Principal Shareholders—Certain Relationships and Related Transactions” and “Election of Directors” in our Proxy Statement for our 2019 Annual Meeting of Shareholders and is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Information about our Audit Committee’s pre-approval policy for audit services, and information on our principal accounting fees and services is reported under the caption “Ratification of the Selection of Our Independent Auditors” in our Proxy Statement for our 2019 Annual Meeting of Shareholders and is incorporated herein by reference.

**PART IV****ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES****(a-1) Financial Statements.**

The following financial statements of BioTime are filed in this Report:

Consolidated Balance Sheets  
 Consolidated Statements of Operations  
 Consolidated Statements of Comprehensive Loss  
 Consolidated Statements of Changes in Shareholders' Equity  
 Consolidated Statements of Cash Flows  
 Notes to Consolidated Financial Statements

**(a-2) Financial Statement Schedules**

Audited financial statements of Asterias are filed as Exhibit 99.1

We will amend this Report to include audited financial statements of OncoCyte for the year ended December 31, 2018. All other schedules are omitted because the required information is inapplicable, or the information is presented in the financial statements or the notes thereto.

**(a-3) Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporation by Reference</b>				<b>Filed Herewith</b>
		<b>Exhibit Number</b>	<b>Filing</b>	<b>Filing Date</b>	<b>File No.</b>	
2.1*	<u>Agreement and Plan of Merger dated November 7, 2018, among BioTime, Inc., Patrick Merger Sub, Inc. and Asterias Biotherapeutics, Inc.</u>	2.1	10-K	November 8, 2018	001-12830	
3.1	<u>Restated Articles of Incorporation, as amended</u>	3.1	10-Q	May 10, 2018	001-12830	
3.2	<u>By-Laws, As Amended</u>	3.1	8-K	September 11, 2017	001-12830	
4.1	Specimen of Common Share Certificate		S-1	December 18, 1991	033-44549	
4.4	<u>Warrant Issued October 1, 2013 to Asterias Biotherapeutics, Inc.</u>	4.1	8-K	September 23, 2014	001-12830	
10.1+		10.23	10-KSB		001-12830	

Edgar Filing: BIOTIME INC - Form 10-K

	<u>Employment Agreement, dated October 10, 2007, between BioTime, Inc. and Michael D. West.</u>			April 14, 2008	
10.2+	<u>Amendment of Employment Agreement, dated November 24, 2015, between BioTime, Inc. and Michael D. West</u>	10.1	8-K	December 1, 2015	001-12830
10.3+	<u>Transition Agreement, dated September 17, 2018, between BioTime, Inc. and Michael D. West</u>	10.3	8-K	September 18, 2018	001-12830
10.4	<u>Commercial License and Option Agreement between BioTime and Wisconsin Alumni Research Foundation</u>	10.1	8-K	January 9, 2008	001-12830
10.5	<u>License Agreement, dated July 10, 2008, between Embryome Sciences, Inc. and Advanced Cell Technology, Inc.</u>	10.32	10-Q	August 14, 2008	001-12830
10.6	<u>First Amendment of Commercial License and Option Agreement, dated March 11, 2009, between BioTime and Wisconsin Alumni Research Foundation</u>	10.38	10-K	March 23, 2009	001-12830

Exhibit Number	Description	Incorporation by Reference			File No.	Filed Herewith
		Exhibit Number	Filing	Filing Date		
10.8+	<u>OrthoCyte Corporation 2010 Stock Option Plan; Form of OrthoCyte Corporation Stock Option Agreement</u>	10.40	10-K	March 23, 2009	001-12830	
10.9+	<u>BioTime Asia, Limited 2010 Stock Option Plan; Form of BioTime Asia Limited Stock Option Agreement</u>	10.42	10-K	March 15, 2011	001-12830	
10.10+	<u>2012 Equity Incentive Plan, as amended</u>	4.1	S-8	July 15, 2015	333-205661	
10.11+	<u>2012 Equity Incentive Plan Form of Employee Incentive Stock Option Agreement</u>	10.7	10-Q	November 12, 2013	001-12830	
10.12+	<u>2012 Equity Incentive Plan Form of Non-employee Director Stock Option Agreement</u>	10.8	10-Q	November 12, 2013	001-12830	
10.13+	<u>2017 Amendment to 2012 Equity Incentive Plan</u>	4.2	S-8	July 7, 2017	333-219204	
10.14+	<u>Cell Cure Neurosciences Ltd. Share Option Plan</u>	10.38	10-K	March 16, 2017	001-12830	
10.15+	<u>Form of Cell Cure Neurosciences Ltd. Share Option Plan Option Agreement</u>	10.39	10-K	March 16, 2017	001-12830	
10.17	<u>Option Agreement, dated March 4, 2014, between BioTime and certain investors</u>	10.59	10-K	March 17, 2014	001-12830	
10.18+	<u>Inducement Option Grant Agreement for Brian Culley</u>					X
10.19**	<u>License Agreement between BioTime, Inc. and Cornell University</u>	10.1	10-Q	November 8, 2011	001-12830	
10.20	<u>Exclusive License Agreement, dated February 15, 2006, between Glycosan BioSystems, Inc. and the University of Utah Research Foundation, as amended</u>	10.1	10-Q	November 9, 2012	001-12830	
10.21+	<u>Employment Agreement, dated December 29, 2014, between BioTime, Inc. Aditya Mohanty</u>	10.64	10-K	March 11, 2015	001-12830	
10.22+	<u>Employment Agreement, dated November 16, 2015, between BioTime, Inc. and Russell Skibsted</u>	10.1	8-K	November 16, 2015	001-12830	
10.23+	<u>Amendment of Employment Agreement, dated November 24, 2015, between BioTime, Inc. and Aditya Mohanty</u>	10.2	8-K	December 1, 2015	001-12830	
10.24	<u>Lease, dated December 10, 2015, between BioTime, Inc. and BSREP Marina Village Owner LLC</u>	10.1	8-K	December 15, 2015	001-12830	
10.25	<u>Cross-License Agreement, dated February 16, 2016, among Asterias Biotherapeutics, Inc., BioTime, Inc., and ES Cell International Pte. Ltd.</u>	10.1	8-K	February 18, 2016	001-12830	
10.26	<u>Controlled Equity OfferingSM Sales Agreement, dated as of April 6, 2017 between BioTime, Inc.,</u>	1.2	S-3	April 6, 2017	333-217182	



10.27	<u>and Cantor Fitzgerald &amp; Co.                  Second Amended and Restated License                  Agreement, dated June 15, 2017, between Cell                  Cure Neurosciences, Ltd. and Hadasit Medical                  Research Services and Development Ltd.                  (Portions of this exhibit have been omitted                  pursuant to a request for confidential treatment)</u>	10.2	10-Q	August 9, 2017	001-12830
10.28+	<u>Debt and Note Purchase Agreement, dated June                  16, 2017, as amended June 29, 2017, between                  BioTime, Inc. and HBL-Hadasit Bio-Holdings                  Ltd. (Portions of this exhibit have been omitted                  pursuant to a request for confidential treatment)</u>	10.3	10-Q	August 9, 2017	001-12830

Exhibit Number	Description	Incorporation by Reference			Filed Herewith	
		Exhibit Number	Filing	Filing Date		File No.
10.29	<u>Share Purchase and Transfer Agreement, dated June 16, 2017, by and among BioTime, Inc. and HBL-Hadasit Bio-Holdings Ltd. and Cell Cure Neurosciences Ltd. (Portions of this exhibit have been omitted pursuant to a request for confidential treatment)</u>	10.4	10-Q	August 9, 2017	001-12830	
10.30	<u>Asset Contribution and Separation Agreement, dated August 17, 2017, between BioTime, Inc. and AgeX Therapeutics, Inc.</u>	10.1	10-Q	November 9, 2017	001-12830	
10.31	<u>License Agreement, dated August 17, 2017, between BioTime, Inc. and AgeX Therapeutics, Inc.</u>	10.2	10-Q	November 9, 2017	001-12830	
10.32	<u>Amendment, dated January 8, 2018, to Second Amended and Restated License Agreement, dated June 15, 2017, between Cell Cure Neurosciences, Ltd. and Hadasit Medical Research Services and Development</u>	10.38	10-K	March 15, 2018	001-12830	
10.33	<u>Stock Purchase Agreement, dated August 30, 2018, between BioTime, Inc., AgeX Therapeutics, Inc. and Juvenescence Limited</u>	10.1	8-K	August 21, 2018	001-12830	
10.34	<u>Convertible Promissory Note, dated August 30, 2018</u>	10.2	8-K	August 21, 2018	001-12830	
10.35	<u>Shareholder Agreement, dated August 30, 2018 between BioTime, Inc. and Juvenescence Limited</u>	10.3	8-K	August 21, 2018	001-12830	
10.36+	<u>Employment Agreement, dated September 17, 2018, between BioTime, Inc. and Brian Culley</u>	10.1	8-K	September 18, 2018	001-12830	
10.37+	<u>Transition Agreement, dated September 17, 2018, between BioTime, Inc. and Aditya P. Mohanty</u>	10.2	8-K	September 18, 2018	001-12830	
10.38+	<u>Employment Agreement, effective January 7, 2019, between BioTime, Inc. and Brandi Roberts</u>					X
21.1	<u>List of Subsidiaries</u>		10-K (1)	March 14, 2019		X
23.1	<u>Consent of OUM &amp; Co. LLP</u>					X
23.2	<u>Consent of OUM &amp; Co. LLP for Financial Statements of Asterias Biotherapeutics, Inc.</u>					X
31.1	<u>Certification of Chief Executive Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated March 14, 2019</u>					X
31.2	<u>Certification of Chief Financial Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002, dated March 14, 2019</u>					X
32.1***						X

Certification of Chief Executive Officer and Chief  
Financial Officer pursuant to 18 U.S.C. Section  
1350, as Adopted Pursuant to Section 906 of the  
Sarbanes-Oxley Act of 2002, dated March 14,  
2019

99.1	<u>Financial Statements of Asterias Biotherapeutics, Inc.</u>	X
101	Interactive Data File	X
101.INS	XBRL Instance Document	X
101.SCH	XBRL Taxonomy Extension Schema	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	X
101.DEF	XBRL Taxonomy Extension Definition Document	X
101.LAB	XBRL Taxonomy Extension Label Linkbase	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	X

\* The schedules and exhibits to the merger agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

\*\* Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

\*\*\* This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

+ Indicates management contract or compensatory plan.

(1) See footnote 1 to the financial statements.

**ITEM 16. FORM 10-K SUMMARY**

None



**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on the 14<sup>th</sup> day of March 2019.

BIOTIME, INC.

By: */s/ Brian M. Culley*  
 Brian M. Culley  
 Chief Executive Officer

Signature	Title	Date
<i>/s/ Brian M. Culley</i> BRIAN M. CULLEY	Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2019
<i>/s/ Brandi Roberts</i> BRANDI ROBERTS	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2019
<i>/s/ Deborah Andrews</i> DEBORAH ANDREWS	Director	March 14, 2019
<i>/s/ Don M. Bailey</i> DON M. BAILEY	Director	March 14, 2019
<i>/s/ Neal C. Bradsher</i> NEAL C. BRADSHER	Director	March 14, 2019
<i>/s/ Stephen C. Farrell</i> STEPHEN C. FARRELL	Director	March 14, 2019
<i>/s/ Alfred D. Kingsley</i> ALFRED D. KINGSLEY	Director	March 14, 2019
<i>/s/ Michael H. Mulroy</i> MICHAEL H. MULROY	Director	March 14, 2019
<i>/s/ Cavan Redmond</i> CAVAN REDMOND	Director	March 14, 2019
<i>/s/ Angus C. Russell</i> ANGUS C. RUSSELL	Director	March 14, 2019



