

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2016

OR

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

For the transition period from _____ to _____

Commission file number 001-33876

Athersys, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

3201 Carnegie Avenue,
Cleveland, Ohio
(Address of principal executive offices)

20-4864095
(I.R.S. Employer
Identification No.)

44115-2634
(Zip Code)

Registrant's telephone number, including area code (216) 431-9900

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

Title of each class
Common Stock, par value \$0.001 per share

Name of each exchange on which registered
NASDAQ Stock Market LLC

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 Securities Exchange Act of 1934. Yes ☐ No ☒

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

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

The aggregate market value at June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, of shares of the registrant's common stock (based upon the closing price per share of \$2.17 of such stock as quoted on the NASDAQ Capital Market on such date) held by non-affiliates of the registrant was approximately \$171.1 million.

The registrant had 109,803,921 shares of common stock outstanding on March 7, 2017.

Documents Incorporated By Reference.

None.

TABLE OF CONTENTS

PART I

| | |
|---|----|
| Item 1. Business | 3 |
| Item 1A. Risk Factors | 20 |
| Item 1B. Unresolved Staff Comments | 33 |
| Item 2. Properties | 33 |
| Item 3. Legal Proceedings | 33 |
| Item 3A. Executive Officers of the Registrant | 33 |
| Item 4. Mine Safety Disclosures | 34 |

PART II

| | |
|--|----|
| Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 35 |
| Item 6. Selected Financial Data | 36 |
| Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations | 37 |
| Item 7A. Quantitative and Qualitative Disclosures About Market Risk | 48 |
| Item 8. Financial Statements and Supplementary Data | 48 |
| Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures | 69 |
| Item 9A. Controls and Procedures | 69 |
| Item 9B. Other Information | 69 |

PART III

| | |
|---|----|
| Item 10. Directors, Executive Officers and Corporate Governance | 70 |
| Item 11. Executive Compensation | 73 |
| Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 86 |
| Item 13. Certain Relationships and Related Transactions, and Director Independence | 88 |
| Item 14. Principal Accountant Fees and Services | 88 |

PART IV

| | |
|---|----|
| Item 15. Exhibits and Financial Statement Schedules | 89 |
| Item 16. Form 10-K Summary | 94 |

PART I

ITEM 1. BUSINESS.

We are an international biotechnology company that is focused primarily in the field of regenerative medicine. We are committed to the discovery and development of best-in-class therapies designed to extend and enhance the quality of human life. We have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple disease areas. Our MultiStem® cell therapy, a patented and proprietary allogeneic stem cell product, is our lead platform product and is currently in later-stage clinical development. Our current clinical development programs are focused on treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, certain pulmonary conditions and other conditions where the current standard of care is limited or inadequate for many patients. These represent major areas of clinical need, as well as substantial commercial opportunities.

We believe our MultiStem therapy represents a potential breakthrough in the field of regenerative medicine and stem cell therapy and could be used to treat a range of disease indications. MultiStem treatment is intended to enhance tissue repair and healing in multiple ways, including reducing inflammatory damage, protecting tissue that is at risk following acute or ischemic injury, and promoting formation of new blood vessels in regions of ischemic injury. These cells appear to be responsive to the environment in which they are administered, by homing to sites of injury and/or organs involved in injury response, and providing active disease response, while producing proteins that may provide benefit in both acute and chronic conditions. In contrast to traditional pharmaceutical products or biologics that generally act through a single biological mechanism of action, MultiStem cell therapy may enhance healing and tissue repair through multiple distinct mechanisms acting in parallel, such as by producing a range of therapeutic factors and dynamically responding to the needs of the body, resulting in a more effective therapeutic response.

We believe the therapeutic and commercial potential for MultiStem cell therapy to be very broad, applying to many areas of significant unmet medical need, and we are pursuing opportunities in several potential multi-billion dollar markets. While traditional pharmaceuticals and biologic therapies typically may be used to treat only a single disease or a narrowly defined set of related conditions, MultiStem cell therapy may have far broader potential and could be developed in different formulations and with different delivery approaches to effectively treat a wide range of disease indications.

The MultiStem product under development would be unique among regenerative medicine approaches because it has the potential to be manufactured on a large scale, may be administered in an “off-the-shelf” manner with minimal processing, and has the potential to augment healing by providing biological potency and therapeutic effects that other cell therapy approaches may not be able to achieve. Additionally, MultiStem treatment has demonstrated good tolerability in both preclinical and clinical studies. Like drugs and biologics, the product is cleared from the body over time, enhancing product safety relative to other types of stem cell therapy. While the product does not permanently engraft in the patient, the therapeutic effects of treatment with MultiStem cells appear to have durability.

We have evaluated the use of MultiStem cell therapy as a potential treatment in several disease areas. Working with an international network of leading investigators and prominent research and clinical institutions, and through our own internal efforts, we have explored the potential for MultiStem therapy to be used as a treatment of acute and chronic forms of neurological conditions, cardiovascular disease, inflammatory and immune disorders, certain pulmonary conditions and other areas of unmet medical need. At present, we have advanced six MultiStem programs into clinical trials. Each of our programs targets an area of significant medical need and represents major commercial market opportunities.

In the neurological area, we evaluated in a completed Phase 2 trial the potential for MultiStem treatment of patients who have suffered neurological damage from an ischemic stroke. The results of this study demonstrated favorable tolerability and safety for MultiStem, consistent with prior studies. While the study did not achieve the primary and component secondary endpoints for the intent-to-treat population, the MultiStem treatment was associated with lower rates of mortality and life threatening adverse events, infections and pulmonary events, and also a reduction in hospitalization and time in the intensive care unit (ICU). In addition, analyses show that patients who received MultiStem treatment earlier (24 to 36 hours post-stroke) in the study’s treatment window had better recovery in comparison to placebo. Analysis of biomarker data obtained from samples of study subjects indicated that MultiStem treatment reduces post-stroke inflammation compared to placebo. Furthermore, it appears that this effect is more pronounced for subjects receiving MultiStem earlier than 36 hours post-stroke. This effect is consistent with our hypothesis regarding mechanisms of action and related preclinical data, and with the clinical data suggesting faster and improved recovery for MultiStem-treated patients relative to current standard of care.

The one-year follow-up data from the Phase 2 trial demonstrated that MultiStem-treated subjects on average continued to improve through one year and had a significantly higher rate of “Excellent Outcome,” as defined below, compared to placebo subjects at one year when evaluating all of the intent-to-treat subjects enrolled in the study. Achievement of an Excellent Outcome is important because it means that a patient has substantially improved in each of the three clinical rating scales used to assess patient improvement and has regained the ability to live and function independently with a high quality of life. The relative improvement in Excellent Outcome was even more pronounced in the study subjects who received MultiStem treatment within 36 hours of the stroke. If the MultiStem therapy is proven effective in a registrational study and receives a marketing authorization from the United States Food and Drug Administration, or FDA, this would represent a substantial increase in the time window for treatment in the United States, which currently is limited to several hours.

Following the completion of our Phase 2 trial and discussions with the regulators, we are engaged in advancing the next stage of clinical development of this program. In January 2016, we established a collaboration with HEALIOS K.K., or Healios, to develop and commercialize MultiStem for the treatment of ischemic stroke in Japan, and the collaboration may be expanded to two other indications, including acute respiratory distress syndrome, or ARDS, and another indication. Healios will be responsible for the development and commercialization of MultiStem for ischemic stroke in Japan on an exclusive basis, and we will receive payments for product supplied to Healios. We have had several interactions with the United States Food and Drug Administration, or FDA, and Japan's Pharmaceuticals and Medical Devices Agency, or PMDA, regarding study design and the potential to accelerate the path to product approval. In September 2016, Athersys received agreement from the FDA under a Special Protocol Assessment, or SPA, for the design and planned analysis of a pivotal Phase 3 clinical study of MultiStem for ischemic stroke, entitled "MultiStem Administration for Stroke Treatment and Enhanced Recovery Study-2," or MASTERS-2, which we intend to be prepared to launch late in 2017. Also, the successful completion of the PMDA's review of the Clinical Trial Notification, or CTN, was announced for Healios' Phase 2/3 trial of MultiStem (HLCM051), entitled "Treatment Evaluation of Acute Stroke Using Regenerative Cell Elements, or TREASURE, allowing Healios to commence a confirmatory clinical trial evaluation of MultiStem cell therapy for treatment of ischemic stroke in Japan. The Healios' TREASURE clinical trial in Japan was presented at the International Stroke Conference in February 2017, and according to Healios, the study is expected to be completed in the second half of 2018. Furthermore, we and Healios intend to take advantage of the new accelerated Regenerative Medicine regulatory framework in Japan that is designed to enable rapid conditional authorization of qualified regenerative medicine therapies. We believe such initiatives could accelerate the commercialization of products like MultiStem cell therapy for ischemic stroke, if future clinical evaluation demonstrates appropriate safety and therapeutic effectiveness.

We are enrolling a Phase 2 clinical study in the United States for the administration of MultiStem cell therapy to patients that have suffered an acute myocardial infarction, or AMI. We were awarded in 2013 a grant from the National Institutes of Health for up to \$2.8 million to support this clinical program. Previously we completed a Phase 1 clinical trial involving administration of MultiStem cell therapy to patients that have suffered an AMI, and the results of this trial demonstrated consistent safety and encouraging evidence of therapeutic benefit among patients with severely compromised heart function.

In addition, we are enrolling a clinical study for the treatment of ARDS in the United Kingdom, or UK, and in the United States. ARDS is a serious immunological and inflammatory condition characterized by widespread inflammation in the lungs. Currently, there are limited interventions and no effective drug treatments for ARDS, making it an area of high unmet clinical need with high treatment costs. In 2015, we and our collaborator, Catapult Therapy Catapult, or Catapult, a not-for-profit center focused on the development of the UK cell therapy industry, were awarded a grant from Innovate UK as partial support of a Phase 1/2 clinical study evaluating the administration of MultiStem cell therapy to ARDS patients.

Additionally, in a completed Phase 1 clinical study, we evaluated the safety, efficacy and potential for MultiStem cell therapy to prevent or reduce graft-versus-host disease, or GvHD, and other complications, and to provide supportive care to patients undergoing a hematopoietic stem cell transplant to treat leukemia or certain other blood borne cancers. Our MultiStem therapy for GvHD has been designated an orphan drug by both the FDA and the European Medicines Agency, or EMA, for the prevention of GvHD, which may provide market exclusivity and other substantial potential incentives and benefits. In 2015, the MultiStem product was granted Fast Track designation by the FDA for prophylaxis therapy against GvHD following hematopoietic cell transplantation. Subsequently, our registration study design received a positive opinion from the EMA through the Protocol Assessment/Scientific Advice procedure. Furthermore, in December 2015, the proposed Phase 2/3 registration study received Special Protocol Assessment designation from the FDA, meaning that the trial is adequately designed to support a Biologic License Application, or BLA, submission for registration if it is successful. Initiation of this trial will depend on the progress in other clinical trials, the achievement of certain business development and financial objectives, and the development and success of alternative treatment options for GvHD that would reduce the need for transplant procedures. We may elect to enter into a development and commercialization collaboration to further advance this program.

MultiStem cell therapy was also evaluated in a Phase 2 clinical study exploring administration of MultiStem to patients with ulcerative colitis, or UC, a common form of inflammatory bowel disease, or IBD, which was conducted by a collaborative partner, Pfizer Inc., or Pfizer. Overall, the study results were disappointing, even though a single administration of the cell therapy may have had some short-term beneficial effects. Taking these results into account and following an internal portfolio review, Pfizer determined that it would not invest further in this program, as would be required by the collaboration, and notified us of this decision to terminate the license agreement effective in the third quarter of 2015. In connection with the termination, all rights that Pfizer had to the program reverted to us, all documents and data were returned to us, and intellectual property generated through the collaboration is owned by us.

[Table of Contents](#)

While development of our clinical programs for human health indications remains our priority, based on our research to date and work performed at our Belgian subsidiary, ReGenesys BVBA, or ReGenesys, we are evaluating our cell therapy for use in treating disease and conditions in the animal health segment, which is an important and growing area. In January 2017, we entered into an evaluation and option agreement with a global leader in the animal health business segment to evaluate our cell therapy technology for application in an undisclosed animal health area. We received a payment in exchange for an exclusive period to evaluate our cell therapy technology with an option to negotiate for a license for the development and commercialization of the technology for the animal health area.

Our development approach has historically involved establishing collaborative relationships with leading research and clinical centers in the United States and internationally. This has enabled us to methodically advance multiple programs in areas of defined unmet medical need in a resource efficient manner. Furthermore, by emphasizing the potential application of our technologies in areas of significant clinical need, we believe we are well positioned to utilize recent regulatory initiatives that are designed to promote the rapid and cost effective development of innovative new therapies, and are actively pursuing such initiatives. These include recent programs in the United States and Europe being implemented by the FDA and the EMA involving existing and potentially broadened application of accelerated review and approval pathways, as well as the new accelerated Regenerative Medicine regulatory framework in Japan that is designed to enable rapid conditional authorization of qualified regenerative medicine therapies. We believe such initiatives could accelerate the development and commercialization of products like MultiStem cell therapy, if clinical results demonstrate appropriate safety and therapeutic effectiveness, thereby increasing shareholder value. To date, Japan's new Regenerative Medicine regulatory framework that was enacted late in 2014 has resulted in the commercial approval of two cell therapy products developed by other companies, and reimbursement of those products, and we hope to also successfully utilize this framework, such as by working with our partner Healios.

In addition to our MultiStem programs, we have other earlier-stage cell-based and small molecule programs targeted at indications with significant unmet medical needs. We may elect to enter into partnerships to advance the development of these programs, as well as certain new programs involving MultiStem therapy.

We were incorporated in Delaware on October 24, 1995. On June 8, 2007, we merged with a wholly owned subsidiary of BTHC VI, Inc., a Delaware corporation, and on August 31, 2007, BTHC VI, Inc. changed its name to Athersys, Inc.

Business Strategy

Our principal business objective is to discover, develop and commercialize novel therapeutic products for disease indications that represent significant areas of clinical need and commercial opportunity. The key elements of our strategy are outlined below:

- *Efficiently Conduct Clinical Development to Establish Clinical Proof of Concept and Biological Activity with our Lead Product Candidates.* We are conducting a number of clinical studies with the intent to establish safety and efficacy proof of concept and/or evidence of biological activity in a number of important disease areas where our cell therapies would be expected to have benefit – including neurological conditions, cardiovascular disease, and inflammatory and immune system dysfunctions. Our strategy is to conduct well-designed studies beginning early in the clinical development process, thus establishing a robust foundation for later-stage development, partnering activity and expansion into complementary areas. We are committed to a rigorous clinical and regulatory approach, which we believe has helped us to advance our programs efficiently, providing high quality, transparent communications and regulatory submissions. Our discussions with the FDA, the EMA and PMDA regulatory agencies have resulted in productive interactions that have helped to advance our programs efficiently.
- *Continue to Refine and Improve our Manufacturing and Related Processes and Deepen our Understanding of Therapeutic Mechanisms of Action.* A key aspect of our MultiStem cells is their expansion capacity *ex vivo* relative to other cell types. This allows for large scale production of the clinical product, which enables greater consistency, specificity and cost of goods advantages over other cell therapies. We are building on this intrinsic biological advantage by advancing and optimizing our production and process development approaches, working with contract manufacturers. We have already begun to optimize new manufacturing techniques and the pharmacy-to-bedside approach to support late-stage development and commercialization of the MultiStem product. We are in the process of developing a large-scale manufacturing process, which if successful, is expected to reduce the cost of the manufactured cells substantially. Additionally, we will continue to refine our understanding of our products' activities and mechanisms of action to enable optimization of administration and dosing and to prepare the foundation for product enhancements and next generation opportunities.

- *Enter into Arrangements with Business Partners to Accelerate Development and Value Creation.* In addition to our internal development efforts, an important part of our strategy is to work with collaborators and partners to accelerate product development, reduce our development costs, and broaden our commercial access. We have entered into licensing and collaborative arrangements with qualified commercial partners to achieve these objectives. We anticipate that this strategy will help us to develop a portfolio of high quality product development opportunities, enhance our clinical development and commercialization capabilities, and increase our ability to generate value from our proprietary technologies. Historically, we entered into technology licensing arrangements with companies such as Healios, Chugai Pharmaceutical Co., Ltd., or Chugai, Pfizer, Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Johnson & Johnson, Wyeth Pharmaceuticals, Inc., RTI Surgical, Inc., or RTI, and others. Licensing partnerships generate revenue and provide capital that allows us to advance our programs further in development.
- *Efficiently Explore New High Potential Therapeutic Applications, Leveraging Third-Party Research Collaborations and our Results from Related Areas.* Our MultiStem product candidate has shown promise in many disease areas, including in treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, and other areas. We are committed to exploring potential clinical indications where our therapies may achieve best-in-class profile, and where we believe we can effectively address significant unmet medical needs. In order to achieve this goal, we established collaborative research relationships with investigators from many leading research and clinical institutions across the United States and Europe, including the Cleveland Clinic, Case Western Reserve University, University of Minnesota, the Medical College of Georgia at Augusta University, the University of Oregon Health Sciences Center, the University of Texas Health Science Center at Houston, the University of Pittsburgh Medical Center, the Katholieke Universiteit Leuven, or KUL, University of Regensburg, and other institutions. Through this network of collaborations, we have evaluated MultiStem therapy in a range of preclinical models that reflect various types of human disease or injury. These collaborative relationships have enabled us to cost effectively explore where MultiStem cell therapy may have relevance and how it may be utilized to advance treatment over current standard of care. Additionally, we have shown that we can leverage clinical safety data and preclinical results from some programs to support accelerated clinical development efforts in other areas, saving substantial development time and resources compared to traditional drug development where each program is separately developed.
- *Continue to Expand our Intellectual Property Portfolio.* We have a broad intellectual property estate that covers our proprietary products and technologies, as well as methods of production and methods of use. Our intellectual property is important to our business and we take significant steps to protect its value. We have ongoing research and development efforts, both through internal activities and through collaborative research activities with others, which aim to develop new intellectual property and enable us to file patent applications that cover new applications of our existing technologies or product candidates, including MultiStem cells and other opportunities. We currently have over 200 patents related to our technologies, providing protection in the United States, Europe, Japan and other areas.

Our Current Programs

By applying our proprietary MultiStem cell therapy product, we established therapeutic product development programs treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, and other conditions. Our programs in the clinical development stage include the following:

- **Ischemic Stroke**: We completed our Phase 2 study of MultiStem treatment of patients suffering a moderate to severe ischemic stroke and announced the one-year follow-up data and final results from the study in February 2016. We are actively engaged in advancing the next stage of clinical development of this program, both independently and with Healios. In September 2016, we announced that we received agreement from the FDA under a SPA for the design and planned analysis of a pivotal Phase 3 clinical trial of MultiStem cell therapy for the treatment of ischemic stroke. The SPA provides agreement from the FDA that the protocol design, clinical endpoints, planned conduct and statistical analyses encompassed in Athersys' planned Phase 3 study are acceptable to support a regulatory submission for approval of the MultiStem product for treating ischemic stroke patients. If the trial is successful, we believe the results from our Phase 3 MASTERS-2 clinical trial, together with other available clinical data, would provide the foundation of the regulatory package to be submitted for marketing approval.

Our MASTERS-2 clinical trial will be a randomized, double-blind, placebo-controlled clinical trial designed to enroll 300 patients in North America and Europe who have suffered moderate to moderate-severe ischemic stroke. The enrolled subjects will receive either a single intravenous dose of MultiStem cell therapy or placebo, administered within 18-36 hours of the occurrence of the stroke, in addition to the standard of care. The primary endpoint will evaluate disability using modified Rankin Scale, or mRS, scores at three months, comparing the distribution, or the “shift” between the MultiStem treatment and placebo groups. The mRS shift analyzes patient improvement across the full disability spectrum, enabling recognition of improvements in disability and differences in mortality and other serious outcomes, among strokes of different severities. The study will also assess Excellent Outcome (the achievement of mRS ≤ 1 , NIHSS ≤ 1 , and Barthel Index ≥ 95) at three months and one year as key secondary endpoints. Additionally, the study will consider other measures of functional recovery, biomarker data and clinical outcomes, including hospitalization, mortality and life-threatening adverse events, and post-stroke complications such as infection.

Also in September 2016, we announced the successful completion of the PMDA review of Healios’ CTN, allowing Healios to commence its confirmatory clinical trial, TREASURE, evaluating the safety and efficacy of administration of MultiStem cell therapy for the treatment of ischemic stroke in Japan, which will be evaluated under the new regulatory framework for regenerative medicine therapies. In accordance with the regulatory system in Japan, a CTN is equivalent to an Investigational New Drug application, or IND, under the regulatory system used in the United States. This clinical trial to be conducted in Japan is part of a partnership and license agreement between Healios and Athersys, focused on the development and commercialization of MultiStem in Japan for the treatment of ischemic stroke, and potentially other indications. The study design was accepted as proposed to PMDA in the CTN.

Healios’ TREASURE study in Japan will be a randomized, double-blind, placebo-controlled clinical trial conducted at hospitals in Japan that have extensive experience at providing care for stroke victims. Based on the experience from our B01-02 study, subjects enrolled in the trial will receive either a single dose of MultiStem or placebo, administered within 18–36 hours of the occurrence of the stroke, in addition to standard of care. The study will evaluate patient recovery through approximately 90 days following initial treatment based on Excellent Outcome and other neurological, functional and clinical endpoints.

We intend to be prepared to launch our MASTERS-2 clinical trial in 2017 and will update our stockholders as we move forward with these plans. The Healios TREASURE clinical trial in Japan was presented at the International Stroke Conference in February 2017, and according to Healios, the study is expected to be complete in the second half of 2018.

- **Acute Myocardial Infarction** : We have an ongoing Phase 2 clinical study in the United States for the administration of MultiStem cell therapy to patients that have suffered an AMI. We previously evaluated the administration of MultiStem to patients that suffered an AMI in a Phase 1 clinical study. The results of this study demonstrated a favorable safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment. This data was published in a leading peer reviewed scientific journal, and one-year follow-up data suggested that the benefit observed was sustained over time. We were awarded a grant in 2013 for up to \$2.8 million in funding to support the advancement of this clinical program, and we are currently enrolling patients in our Phase 2 clinical study, evaluating the safety and efficacy of MultiStem treatment in subjects who have a non-ST elevated myocardial infarction. The study is double-blind, sham-controlled and is being conducted at leading cardiovascular centers in the United States. Since the rate of enrollment in this study has been below our expectations based on our historical data, we have taken steps to increase enrollment rates that have recently been implemented.

- **Acute Respiratory Distress Syndrome** : We have also initiated a clinical study for the treatment of ARDS in the UK and in the United States. In 2015, we were awarded a grant from Innovate UK for up to approximately £2.0 million as partial support of a Phase 1/2 clinical study evaluating the administration of MultiStem cell therapy to ARDS patients. ARDS is a serious immunological and inflammatory condition characterized by widespread inflammation in the lungs that severely compromises pulmonary function, requiring patients to be placed on a ventilator. ARDS can be triggered by pneumonia, sepsis, or other trauma and represents a major cause of morbidity and mortality in the critical care setting. The Phase 1/2 clinical trial is active, although initial patient accrual has been slower than expected, and we have taken steps to improve enrollment.

- **Hematopoietic Stem Cell Transplant / GvHD** : We completed a Phase 1 clinical study of the administration of MultiStem cell therapy to patients suffering from leukemia or certain other blood-borne cancers in which patients undergo radiation therapy and then receive a hematopoietic stem cell transplant. Such patients are at significant risk for serious complications, including GvHD, an imbalance of immune system function caused by transplanted cells that trigger an attack against various tissues and organs in the patient. Data from the study demonstrated the safety of MultiStem cell therapy in this indication and suggested that the treatment may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. We were granted orphan drug designation by the FDA and the EMA, for MultiStem treatment in the prevention of GvHD. In 2015, the MultiStem product was granted Fast Track designation by the FDA for prophylaxis therapy against GvHD following hematopoietic cell transplantation. Subsequently, our registration study design received a positive opinion from the EMA through the Protocol Assessment/Scientific Advice procedure. Furthermore, in December 2015, the proposed registration study received Special Protocol Assessment designation from the FDA, meaning that the trial is adequately designed to support a biologics license application, or BLA, submission for registration if it is successful. Currently, we are staging this program for future registration-directed development dependent on the achievement of certain business development and financial object and the development and success of alternative therapies for treating the underlying conditions leading to transplant.

[Table of Contents](#)

While development of our clinical programs for human health indications remains our priority, based on our research to date and work performed at ReGenesys, we are evaluating our cell therapy for use in treating disease and conditions in the animal health segment. We and ReGenesys have demonstrated in preclinical animal health models that MultiStem cell therapy can promote tissue repair and healing that could provide meaningful benefits to animal patients, including those suffering from conditions with unmet medical need. In January 2017, we entered into an evaluation and option agreement with a global leader in the animal health business segment to evaluate our cell therapy technology for application in an undisclosed animal health area. We received a payment in exchange for an exclusive period to evaluate our cell therapy technology with an option to negotiate for a license for the development and commercialization of the technology for the animal health area.

We are engaged in preclinical development and evaluation of MultiStem therapy in other indications, focusing on the neurological, cardiovascular and inflammatory and immune disease areas, and we conduct such work both through our own internal research efforts and through a broad global network of collaborators. We are routinely in discussions with third parties about collaborating in the development of MultiStem therapy for various programs and may enter into one or more business partnerships to advance these programs over time.

As the MultiStem product platform continues to advance, we are increasingly engaged in process development initiatives intended to increase manufacturing scale, reduce production costs, and enhance process controls and product quality, among other things. These initiatives are being conducted both internally and outsourced to select contractors, and the related investments are meant to enable us to meet potential commercial demand in the event of regulatory approval.

In January 2016, we entered into a license agreement with Healios to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan, and to provide Healios with access to our proprietary technologies for use in Healios' proprietary "organ bud" program, initially for transplantation to treat liver disease or dysfunction. Under the agreement, Healios also obtained a right to expand the scope of the collaboration to include the exclusive rights to develop and commercialize MultiStem for the treatment of two additional indications in Japan, which include ARDS and another indication in the orthopedic area, as well as all indications for the "organ bud" program. Healios is working toward the development and commercialization of the MultiStem product in Japan, and we are providing the manufactured product to Healios for its clinical studies.

We also have a collaboration with RTI for the development of products for certain orthopedic applications using our stem cell technologies in the bone graft substitutes market, and we have been earning royalty revenue from product sales since 2014 and may receive other payments upon the successful achievement of certain commercial milestones.

We have also developed other earlier stage cell-based and small molecule programs targeted at indications with significant unmet needs. We may elect to enter into partnerships to advance the development of these programs, as well as certain programs involving MultiStem therapy.

Regenerative Medicine Programs

MultiStem — A Novel Therapeutic Modality

We are developing our MultiStem therapy, a proprietary non-embryonic, allogeneic stem cell product candidate, that we believe has potential utility for treating a broad range of diseases and could have widespread application in the field of clinical regenerative medicine. Unlike traditional bone marrow transplants or other stem cell therapies, MultiStem cells may be manufactured on a large scale and may be administered without tissue matching or the need for immune suppression, analogous to type O blood. Potential applications of MultiStem therapy include the treatment of cardiovascular disease, neurological disease or injury and conditions involving the immune system, including autoimmune disease and other conditions. We believe that the MultiStem therapy represents a significant advancement in the field of stem cell therapy and could have broad clinical application. We currently have open INDs for the study of MultiStem administration in distinct clinical indications, and several of our programs are in later-stage clinical development.

MultiStem cell therapy is a patented biologic product that is manufactured from human stem cells obtained from adult bone marrow, although these cells may alternatively be obtained from other tissue sources. The product consists of a special class of human stem cells that have the ability to express a range of therapeutically relevant proteins and other factors, as well as form multiple cell types. Factors expressed by the cells have the potential to deliver a therapeutic benefit in several ways, such as the reduction of inflammation, regulation of immune system function, protection of damaged or injured tissue, the formation of new blood vessels in regions of ischemic injury and augmentation of tissue repair and healing in other ways. Like drugs, these cells may be stored for an extended period of time in frozen form and used off-the-shelf. Following administration, the cells have been shown to express multiple therapeutically relevant proteins, but unlike a traditional transplant, are subsequently cleared from the body over time, analogous to a drug or biologic.

We believe that MultiStem represents a potential best-in-class stem cell therapy because it exhibits each of the following characteristics based on research and development conducted to date:

- *Broad plasticity and multiple potential mechanisms of action.* MultiStem cells have a demonstrated ability in animal models to form a range of cell types and also appear to be able to deliver therapeutic benefit by producing factors that protect tissues against damage and inflammation, as well as enhancing or playing a direct role in revascularization or tissue regeneration.
- *Large-scale production.* Unlike conventional stem cells, such as blood-forming or hematopoietic stem cells, mesenchymal stem cells, or other cell types, MultiStem cells have the potential to be produced on a large scale, processed, and cryogenically preserved, and then used clinically in a rapid and efficient manner. Material obtained from a single donor may be used to produce hundreds of thousands or millions of individual doses, representing a yield far greater than other stem cells have been able to achieve.
- *“Off-the-shelf” utility.* Unlike traditional bone marrow or hematopoietic stem cell transplants that require extensive genetic matching between donor and recipient, MultiStem administration does not require tissue matching or immune suppressive drugs. The MultiStem product is administered as a cryogenically preserved allogeneic product, meaning that these cells are not genetically matched between donor and recipient. This feature, combined with the ability to establish large MultiStem banks, could make it practical for clinicians to efficiently deliver stem cell therapy to a large number of patients.
- *Safety.* Other stem cell types, such as undifferentiated embryonic stem cells or induced pluripotent stem cells have shown the capacity to form ectopic tissue or teratomas, which are tumor-like growths. These could pose serious safety risks to patients. In contrast, MultiStem cells have shown a consistent and favorable tolerability profile that has been compiled over several years of preclinical study in a range of animal models by a variety of investigators and that is supported by clinical data generated to date.

At each step of the MultiStem production process, cells are analyzed according to pre-established criteria to ensure that a consistent, well characterized product candidate is produced. Cells are harvested from a pre-qualified, healthy, consenting donor and these cells are then expanded to form a master cell bank from which we subsequently produce clinical grade material. We demonstrated the ability to harvest cells that meet our rigorous criteria from healthy donors with a high degree of consistency. Furthermore, in multiple animal models, MultiStem has been shown to be non-immunogenic, and is administered without the genetic matching that is typically required for conventional bone marrow or stem cell transplantation.

The distinctive profile of the MultiStem product allows us to pursue multiple high value commercial opportunities from a single product platform. Based upon work that we and independent collaborators have conducted over the past several years, we believe that MultiStem cells have the potential to treat a range of distinct disease indications, including ischemic injury and cardiovascular disease, certain types of neurological conditions or injury, autoimmune disease, transplant support (including in oncology patients and solid organ transplant areas), and a range of orphan disease indications. As a result, we believe we will be able to leverage our foundation of safety and efficacy data to add clinical indications efficiently, enabling us to reduce development costs and timelines substantially.

MultiStem for Treating Neurological Conditions, Cardiovascular Disease, and Inflammatory and Immune Disorders

Healthcare represents a significant part of the global economy. In the United States, it represented approximately 17.5% of all economic activity in 2014, or about \$3.0 trillion dollars, annually. However, the United States, along with many other nations, is experiencing an unprecedented demographic shift that is resulting in a significantly expanded population of older individuals. According to United States Census data, in the next few years there will be a dramatic increase in the number of individuals over the age of 65, as this segment of the population increases from 40.2 million individuals in 2010 to more than 72 million people in 2030, representing an increase of approximately 80%. The aging of the population will create enormous financial pressure on the healthcare system in the United States and other countries around the world, resulting in significant clinical challenges, but also resulting in substantial commercial opportunities.

Data from the National Center for Health Statistics shows that as people get older, they are more susceptible to a variety of age related conditions, including heart disease, stroke, certain forms of cancer, diabetes, progressive neurological disorders, various chronic inflammatory and immune conditions, renal disease and a range of others. As a consequence, as people get older they spend far more on healthcare. On average, they spend four to ten times more on healthcare annually at age 65 or beyond than when they were younger and more healthy. According to the Alliance for Aging Research, 83% of healthcare spending is associated with chronic conditions, and other research shows that 62% of healthcare spending is associated with multiple chronic conditions. Traditional medical approaches have failed to adequately address this problem.

We have worked with independent investigators at a number of leading institutions, such as the Cleveland Clinic, Case Western Reserve University, University of Minnesota, the National Institutes of Health, the Medical College of Georgia at Augusta University, the University of Oregon Health Sciences Center, the University of Texas Health Science Center at Houston, KUL, the University of Pittsburgh Medical Center, University of Regensburg and other institutions. Through this network of collaborations, we studied the impact of MultiStem cell therapy in a range of preclinical models that reflect various types of human disease or injury in the neurological, cardiovascular, and immunological areas. To date, we and our collaborators have published research results illustrating the potential benefits of MultiStem cell therapy in a range of indications including ischemic stroke, traumatic brain injury, or TBI, brain damage due to restricted blood flow in newborns, spinal cord injury, myocardial infarction, vascular disease, acute pulmonary distress, and bone marrow transplant support/GvHD. In addition, we have explored and intend to further explore MultiStem administration in the treatment of a range of other conditions, including other forms of cardiovascular disease, neurological conditions, and immune related disorders.

Based on preclinical results, we have advanced MultiStem therapy to clinical development stage in several clinical indications or disease areas: treatment for stroke caused by a blockage of blood flow in the brain; treatment of damage caused by myocardial infarction; treatment for ARDS; support in the hematologic malignancy setting to reduce certain complications associated with traditional bone marrow or hematopoietic stem cell, or HSC, transplantation; and treatment of IBD, initially focused on UC. Additionally, in collaboration with a leading transplant center in Europe, we advanced a program in the solid organ transplant area into clinical development.

We may expand to other clinical indication areas as results warrant and resources permit.

Neurological Injury and Disease — MultiStem for Ischemic Stroke

Another focus of our regenerative medicine program is MultiStem administration for the treatment of neurological injury as a result of acute or chronic conditions. Neurological injury and disease represents an area of significant unmet medical need, a major burden on the healthcare system, and also represents a huge commercial opportunity.

Many neurological conditions require extensive long-term therapy, and many require extended hospitalization and/or institutional care, creating an enormous cost burden. Stroke represents an area where the clinical need is particularly significant, since it represents a leading cause of death and significant long term disability. We have published research with independent collaborating investigators that demonstrates that MultiStem administration conveys biological benefits in preclinical models of ischemic stroke, as well as other models of neurological damage and injury, including TBI, neonatal hypoxic ischemia (a cause of neurological damage in infants), and spinal cord injury. We also conducted preclinical work in other neurological areas, and have been awarded grants to support work in areas such as the indications described above and for evaluating the potential of MultiStem cells to address chronic conditions such as Multiple Sclerosis, or MS, or Parkinson's disease. Our research has shown that MultiStem cells convey benefits through distinct mechanisms, including reducing inflammatory damage, protecting at risk tissue at the site of injury, and through direct neurotrophic effects that stimulate the recovery of damaged neurons. As a result, we believe that MultiStem therapy may have relevance to multiple forms of neurological injury and disease.

Our initial clinical focus in the neurological area involves evaluating MultiStem administration to treat ischemic stroke. Currently, there are approximately 800,000 individuals in the United States that suffer a stroke each year, more than two million stroke victims in the United States, Europe and Japan combined and more than 16.9 million people that suffer a stroke each year globally. The vast majority of these (approximately 85% to 90%) are ischemic strokes, that are caused by a blockage of blood flow in the brain, that cuts off the supply of oxygen and nutrients, and can result in tissue loss and neurological damage, as well as long term or permanent disability. The remaining 10% to 15% are hemorrhagic strokes, which occur when a blood vessel bursts and bleeding into the brain ensues.

Despite the fact that ischemic stroke is one of the leading causes of death and disability in the United States, there has been limited progress toward the development of treatments that improve the prognosis for stroke victims. The only FDA-approved drug currently available for ischemic stroke is the anti-clotting factor, tPA. According to current clinical guidelines, tPA must be administered to stroke patients within several hours after the occurrence of the ischemic stroke to remove the clot while minimizing potential risks, such as bleeding into the brain. Administration of tPA after three to four hours is not recommended, since it can cause cerebral bleeding or even death. Recent advancements in the development of clot extraction devices may help additional patients, but such treatments are limited to certain types of strokes and to an early time window. As a consequence of this limited time window, only a small percentage of stroke victims are treated with the currently available therapy—most simply receive supportive or “palliative” care. The long-term costs of stroke are substantial, with many patients requiring extended hospitalization, extended physical therapy or rehabilitation (for those patients that are capable of entering such programs), and many require long-term institutional or family care.

In preclinical studies conducted by investigators, including at the University of Minnesota, the Medical College of Georgia at Augusta University, and the University of Texas Health Science Center at Houston, significant functional improvements have been observed in rodents that have undergone an experimentally induced stroke, or that have incurred significant neurological damage due to similar types of ischemic events or acute injury, such as a result of neonatal hypoxic ischemia or TBI, and then received MultiStem treatment. Published research has demonstrated that MultiStem administration even one week after a surgically induced stroke results in substantial long-term therapeutic benefit, as evidenced by the improvement of treated animals compared with controls in a battery of tests examining mobility, strength, fine motor skills, and other aspects of neurological functional improvement. We believe MultiStem treatment conveys significant benefits through several mechanisms, including reduction of inflammation and immune system modulation in the ischemic area, and the protection and rescue of damaged or injured cells, including neuronal tissue. Pre-clinical research results presented at the 2012 American Heart Association International Stroke Conference demonstrated that MultiStem administration 24 hours following a stroke reduced inflammatory damage in the brain and resulted in significant functional improvement, and that some of these results were achieved by reducing the inflammatory response emanating from the spleen in animal models. These results confirmed that MultiStem treatment is well tolerated, does not require immunosuppression and results in a robust and durable therapeutic benefit, and are consistent with prior results that show MultiStem can provide significant benefits even when administered up to one week after the initial stroke event, although earlier treatment (e.g. within 24 hours post stroke) provided more substantial benefits in these preclinical studies.

We completed our first clinical study in stroke, which was a double-blind, placebo-controlled Phase 2 clinical trial exploring the administration of MultiStem to patients that have suffered an ischemic stroke in the United States and Europe. The results of this study demonstrated favorable safety and tolerability for MultiStem, consistent with prior clinical studies in other indications. While the study did not achieve the primary and component secondary endpoints for the intent-to-treat population, the MultiStem treatment was associated with lower rates of mortality and life threatening adverse events, infections and pulmonary events, and also a reduction in hospitalization. In addition, analyses show that patients who received MultiStem treatment earlier (24 to 36 hours post-stroke) in the study’s treatment window had better recovery in comparison to placebo, and this treatment effect appeared to be more pronounced the earlier the MultiStem administration occurred within this timeframe. Analysis of biomarker data obtained from samples of study subjects indicated that MultiStem treatment reduces post-stroke inflammation compared to placebo. Furthermore, it appears that this effect is more pronounced for subjects receiving MultiStem earlier than 36 hours post-stroke. This effect is consistent with our hypothesis regarding mechanisms of action and related preclinical data, and with the clinical data suggesting faster recovery for MultiStem-treated patients. One-year follow-up data demonstrated that MultiStem-treated subjects on average continued to improve through one year post-treatment and achieved a significantly higher rate of Excellent Outcome compared to placebo subjects in the intent-to-treat population. We are focused on advancing this program to the next stage of clinical development, which is our FDA-approved MASTERS-2 Phase 3 study. If proven effective, this would represent a substantial increase in the time window for treatment of stroke victims, which currently is limited to several hours.

We are also interested in the application of MultiStem for other neurological indications that represent areas of significant unmet medical need, such as TBI, which represents the leading cause of disability among children and young adults, and a leading cause of death. Approximately 1.7 million cases of TBI are seen in the United States each year, nearly half a million cases of which are children age 0 to 14 years old. The United States Center for Disease Control and Prevention, or CDC, estimates that more than 5.3 million individuals are living with a disability and have a long-term or lifelong need for help to perform activities of daily living as a result of a TBI. The annual direct and indirect costs for TBI are approximately \$60 billion a year, according to the National Institute of Neurological Disorders and Stroke, which is part of the National Institutes of Health, or NIH. In preclinical studies of TBI, administration of MultiStem dramatically reduced the extent of damage caused by a TBI, and promoted accelerated healing of the blood-brain barrier. In 2012, we announced grant funding of up to \$3.6 million to further advance our MultiStem programs and cell therapy platform, including further development of MultiStem therapy for the treatment of TBI and further development of our cell therapy formulations and manufacturing capabilities. We were authorized to advance our TBI program into the final phase of the federal grant award, to be completed in 2017. Upon completion of this research, we expect to be in a position to file an IND for the clinical development of MultiStem for treating TBI, if we elect to move the program forward into clinical development.

We are also conducting preclinical work exploring the application of MultiStem treatment in other neurological indications. In 2012, we presented data at the Annual Society for Neuroscience meeting that demonstrated that intravenous MultiStem administration one day after spinal cord injury, or SCI, results in statistically significant and sustained improvements in gross locomotor function, fine locomotor function and bladder control compared to control treated animals. In 2015, we published new findings from a peer-reviewed study in Nature's *Scientific Reports* that showed that MultiStem cell therapy was effective in improving the health and recovery of animals following an acute SCI. Intravenous administration of our cells one day after injury prevented loss of spinal cord tissue, resulting in significant improvement of walking function and urinary control. Further, in 2015, we published an article in the peer-reviewed *Journal of Neuroinflammation* that provides further evidence that MAPC cells have the potential to provide benefit following hypoxic ischemia, an injury caused by oxygen deprivation to the brain before or during birth and a leading cause of cerebral palsy. The article also describes the biological mechanisms through which this cell therapy delivers benefit. These findings are consistent with previous findings in related areas, such as ischemic stroke, and add to the scientific foundation supporting MultiStem cell therapy for the treatment of acute neurological injuries.

Over the past several years, we have been utilizing grant funding to investigate the potential for MultiStem treatment for chronic progressive MS based on initial results in preclinical models. Our previous work, supported by Fast Forward and the National Multiple Sclerosis Society, demonstrated the potential benefits of MultiStem therapy for treating MS. Using several preclinical models of MS, researchers observed that MultiStem cell administration results in sustained behavioral improvements, arrests the demyelination process and supports remyelination of affected axons. More recently, we have focused on the mechanism of action underlying the enhanced remyelination in vivo and shown that MultiStem cells and secreted factors increase differentiation of oligodendrocytes. We intend to continue to advance our MS program upon additional grant support with our collaborators at George Washington University.

Cardiovascular Disease — Evaluating MultiStem for Treating Damage from a Heart Attack

Cardiovascular disease is an area of significant clinical need and its prevalence is expected to grow in the years ahead. Despite treatment advances in recent years, cardiovascular disease remains the leading cause of death and represents one of the leading causes of disability around the world. In the United States, approximately 905,000 people suffer a heart attack each year, and approximately 5.7 million individuals in the United States were suffering from heart failure in 2012, according to the American Heart Association 2016 Statistical Update. Another 8.5 million people suffer from peripheral arterial disease, which is associated with significant morbidity and mortality. In addition, in 2013, there were approximately 801,000 deaths (or ≈ 1 of every 3 deaths in the United States) that occurred from all forms of cardiovascular disease, including approximately 655,000 individuals that died as a result of coronary heart disease or heart failure. According to projections published by the American Heart Association in 2016, aggregate costs for treating heart disease in the United States are expected to soar in the coming years. In 2016, annual direct costs for treating cardiovascular disease were \$555 billion, but by 2035, these are expected to nearly double to a projected \$1.1 trillion per year.

In a Phase 1 clinical trial, we explored MultiStem treatment for damage caused by AMI. Myocardial infarction is one of the leading causes of death and disability in the United States and is caused by the blockage of one or more arteries that supply blood to the heart. Such blockages can be caused, for example, by the rupture of an atherosclerotic plaque deposit. A variety of risk factors are associated with an elevated risk of myocardial infarction or atherosclerosis, including age, high blood pressure, smoking, sedentary lifestyle and genetics. While advances in the diagnosis, prevention and treatment of heart disease have had a positive impact, there is clearly room for improvement—myocardial infarction remains a leading cause of death and disability in the United States and the rest of the world.

MultiStem treatment has been studied in validated animal models of AMI, including at both the Cleveland Clinic and the University of Minnesota. Investigators demonstrated that the administration of allogeneic MultiStem cells into the hearts of animals damaged by experimentally induced heart attacks resulted in significant functional improvement in cardiac output and other functional parameters compared with animals that received placebo or no treatment. Furthermore, the administration of immunosuppressive drug was not required and provided no additional benefit in this study, and supports the concept of using MultiStem cells as an allogeneic product. We completed additional preclinical studies in established pig models of AMI using catheter delivery and examining various factors such as the route and method of MultiStem administration, dose ranging, and timing of treatment.

We conducted a multicenter, open-label Phase 1 clinical trial in this indication and the results showed that MultiStem treatment was well tolerated at all dose levels, exhibited a favorable safety profile, and that patients who received MultiStem treatment exhibited meaningful improvements in cardiovascular function, including left ventricular ejection fraction, wall motion scores, and other parameters. These results were published by *Circulation Research* in 2012.

We are enrolling a Phase 2 clinical study for the administration of MultiStem cell therapy to patients that have suffered an AMI. We were awarded a grant in 2013 for up to \$2.8 million in funding from the NIH to support the advancement of this clinical program, and we are currently enrolling patients in our Phase 2 study evaluating the safety and efficacy of MultiStem treatment in subjects who have a non-ST elevated myocardial infarction. The study is double-blind, sham-controlled and is being conducted at leading cardiovascular centers in the United States.

Immunological Disorders — MultiStem for Acute Pulmonary Distress, IBD and HSC Transplant Support

Inflammatory and immune disorders represent a significant burden to society. There are over 80 recognized autoimmune disorders, which are conditions caused by an acute or chronic imbalance in the immune system. In these conditions, cells of the immune system begin to attack certain tissues or organs in the body, resulting in tissue damage and loss of function. Some inflammatory and immune conditions are associated with age-related conditions (e.g., rheumatoid arthritis), but some are due to other causes that may be genetic, environmental or a combination of both (e.g., Type 1 diabetes, IBD). Still other conditions may reflect complications associated with the treatment of other conditions (e.g., GvHD, a frequent complication associated with transplant procedures used to treat leukemia or related blood-borne cancers). Each of these conditions shares certain biological characteristics, in that the immune system imbalance results from the inappropriate activation of certain populations of immune cells that subsequently results in significant tissue damage and destruction. This immune imbalance may result in a complex cascade of inflammation that can result in pain, progressive tissue deterioration and loss of function. While currently available immunomodulatory drugs have proven to be effective for some patients, they have failed to adequately address the needs of many other patients that suffer from inflammatory and immune disorders.

In both preclinical and clinical studies, MultiStem cells have shown potent immunomodulatory properties, including the ability to reduce active inflammation through various modes of action, stimulate tissue repair and restore immune system balance. Accordingly, we believe that MultiStem therapy could have broad application in the area of treating immune system disorders, including certain acute inflammatory conditions, autoimmune diseases and other conditions.

In animal models, MultiStem cells have demonstrated an ability to reduce the severity of pulmonary distress, reduce alveolar edema and return lung endothelial permeability to normal. Intravenous MultiStem treatment early following the onset of the condition may ameliorate the initial hyper-inflammation and reduce the fibrotic activity that follows, thereby speeding the return to and improving the likelihood of more normal lung function, and helping patient recovery.

ARDS is a serious immunological and inflammatory condition characterized by widespread inflammation in the lungs. ARDS can be triggered by pneumonia, sepsis, or other trauma and represents a major cause of morbidity and mortality in the critical care setting. It has significant implications, as it prolongs intensive care unit, or ICU, and hospital stays, and requires convalescence in the hospital and rehabilitation. There are limited interventions and no effective drug treatments for ARDS, making it an area of high unmet clinical need with high treatment costs. Given ARDS high treatment costs, a successful cell therapy could be expected to generate significant savings for the healthcare system by reducing days on a ventilator, days in the intensive care unit and total days in the hospital, and could reduce mortality and morbidity, as well as improve quality of life for those suffering from the condition. The medical need for a safe and effective treatment of ARDS is significant due to its high mortality rate, and it affects annually approximately 33,000 patients in the UK and 400,000 to 500,000 patients in Europe, the United States and Japan, alone.

In January 2015, we announced that our subsidiary, Athersys Limited, received a grant award of up to approximately £2.0 million from Innovate UK as partial support of a Phase 1/2 clinical study evaluating the administration of MultiStem cell therapy to ARDS patients. We initiated this study in 2016 in both the UK and the United States, and it is currently enrolling patients.

Another area of focus is the use of MultiStem cells as adjunctive treatment for HSC/bone marrow transplant used as therapy in hematologic malignancy. For many types of cancer, such as leukemia or other blood-borne cancers, treatment typically involves radiation therapy or chemotherapy, alone or in combination. Such treatment can substantially deplete the cells of the blood and immune system, by reducing the number of stem cells in the bone marrow from which they arise. The more intense the radiation treatment or chemotherapy, the more severe the resulting depletion is of the bone marrow, blood, and immune system. Other tissues may also be affected, such as cells in the digestive tract and in the pulmonary system. The result may be severe anemia, immunodeficiency, substantial reduction in digestive capacity, and other problems that may result in significant disability or death.

[Table of Contents](#)

One strategy for treating the depletion of bone marrow is to perform a peripheral blood stem cell transplant or a bone marrow transplant. This approach may augment the patient's ability to form new blood and immune cells and provide a significant survival advantage. However, finding a closely matched donor is frequently difficult or even impossible. Even when such a donor is found, in many cases there are immunological complications, such as GvHD, which may result in serious disability or death.

Working with leading experts in the stem cell and bone marrow transplantation field, we studied MultiStem in animal models of radiation therapy and GvHD. In multiple animal models, MultiStem cells have been shown to be non-immunogenic, even when administered without the genetic matching that is typically required for conventional bone marrow or stem cell transplantation. Furthermore, in animal model systems testing immune reactivity of T-cells against unrelated donor tissue, MultiStem has been shown to suppress the T-cell-mediated immune responses that are an important factor in causing GvHD. MultiStem-treated animals also displayed a significant increase in survival relative to controls. As a result, we believe that MultiStem administration in conjunction with or following standard HSC transplantation may have the potential to reduce the incidence or severity of complications and may enhance gastrointestinal function, which is frequently compromised as a result of radiation treatment or chemotherapy.

We completed a Phase 1 clinical trial examining the safety and tolerability of a single dose or repeat dosing of MultiStem cells administered intravenously to patients receiving a bone marrow or hematopoietic stem cell transplant as part of their treatment of leukemia or other hematological condition. The trial was an open label, multicenter trial that involved leading experts in the field of bone marrow transplantation. In 2012, we announced the top-line results from the trial. We observed a consistent safety profile in both the single and multiple dose arms of the study, and at all dose levels tested. Although the trial was not specifically designed to demonstrate efficacy, we also observed clinically meaningful improvement in medically important parameters relative to historical clinical experience, including reduced incidence and severity of acute GvHD, improved relapse free survival, no graft failures, and enhanced engraftment rates relative to other forms of treatment.

We were granted orphan drug designation by the FDA and the EMA for MultiStem treatment in the prevention of GvHD. In February 2015, the MultiStem product was granted Fast Track designation by the FDA for prophylaxis therapy against GvHD following hematopoietic cell transplantation. Subsequently, our registration study design received a positive opinion from the EMA through the Protocol Assessment/Scientific Advice procedure. Furthermore, in December 2015, the proposed registration study received Special Protocol Assessment designation from the FDA, meaning that the trial is adequately designed to support a BLA submission for registration if it is successful.

Other Programs

Animal Health Care

While development of our clinical programs for human health indications remains our priority, based on our research to date and work performed at our Belgian subsidiary, ReGenesys, we have demonstrated in preclinical animal health models that MultiStem cell therapy can promote tissue repair and healing that could provide meaningful benefits to animal patients, including those suffering from serious conditions with unmet medical need. According to Future Market Insights (FMI) and other analysts, the global animal healthcare market was estimated to be valued at approximately \$32 billion in 2015 and is expected to grow to more than \$43 billion by 2020, reflecting a compound annual growth rate of more than 5% during this period. The companion animal segment is a particularly fast growing area, projected to exceed more than \$15 billion by 2020. In January 2017, we entered into an evaluation and option agreement with a global leader in the animal health business segment to evaluate our cell therapy technology for application in an undisclosed animal health area. We received a payment in exchange for an exclusive period to evaluate our cell therapy technology with an option to negotiate for a license for the development and commercialization of the technology for the animal health area.

Novel 5HT_{2c} agonists for the treatment of obesity and other conditions

We have developed novel pharmaceutical treatments for obesity, which are compounds designed to act by stimulating a key receptor in the brain that regulates appetite and food intake—the 5HT_{2c} receptor. In 2012, the FDA approved Belviq (Lorcaserin), a 5HT_{2c} agonist, for the treatment of obesity, illustrating that the FDA agrees with the concept that 5HT_{2c} agonists that display appropriate selectivity, biological activity and clinical safety are approvable for indications such as obesity. We believe that the potency and selectivity profile displayed by our compounds in a clinical setting will result in substantially better efficacy and a cleaner safety and tolerability profile, as well as a more convenient dosing schedule than other 5HT_{2c} agonist programs, including Lorcaserin. Further, we have observed efficacy when these compounds were evaluated in preclinical models of schizophrenia. We may elect to enter into a partnership to advance the development of our 5HT_{2c} agonist program, either for the treatment of obesity, schizophrenia, or both indications, as well as for certain programs involving MultiStem.

Collaborations and Partnerships

Healios

On January 8, 2016, we entered into a license agreement with Healios to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan, and to provide Healios with access to Athersys' proprietary MAPC technology for use in Healios' "organ bud" program, initially for transplantation to treat liver disease or dysfunction. Under the agreement, Healios also obtained a right to expand the scope of the collaboration to include the exclusive rights to develop and commercialize MultiStem for the treatment of two additional indications in Japan, which include ARDS and another indication in the orthopedic area, and to include all indications for the "organ bud" program. Healios is developing and intends to commercialize the MultiStem product in Japan, and we are using commercially reasonable efforts to supply manufactured product to Healios for its clinical trial. In the event that we determine that we are not able to supply product at a defined price or a price otherwise agreeable to Healios, we may notify Healios and grant it a license to make the product solely for use in the licensed field in Japan. In January 2017, we signed a clinical trial supply agreement, which is consistent with the license agreement, in preparation for delivering these planned manufacturing services for Healios' clinical trial in Japan.

Under the terms of the agreement, we received an up-front cash payment of \$15 million from Healios, and the collaboration can be expanded at Healios' election. If Healios expands the collaboration, we will be entitled to receive a cash payment of \$10 million. Healios may exercise its option to expand the collaboration after it receives the initial results from Athersys' ongoing ARDS clinical trial.

For the ischemic stroke indication, we may also receive additional success-based development and regulatory approval and potential sales milestones aggregating up to \$225 million. We will also receive tiered royalties on product sales, starting in the low double digits and increasing incrementally into the high teens depending on net sales levels. Following the expiration or termination of the Agreement, Healios shall pay reduced royalties for continued use of our trademarks. Additionally, we will receive payments for product supplied to Healios under a manufacturing supply agreement.

If Healios exercises the option to expand the collaboration, we would be entitled to receive royalties from product sales and success-based development, regulatory approval and sales milestones, as well as payments for product supply related to the additional indications covered by the option.

For the "organ bud" product, we are entitled to receive a fractional royalty percentage on net sales of the "organ bud" products and will receive payments for manufactured product supplied to Healios under a manufacturing supply agreement. Additionally, we have a right of first negotiation for commercialization of an "organ bud" product in North America, with such right expiring on the later of (i) the date five years from the effective date of the Agreement and (ii) 30 days after authorization to initiate clinical studies on an "organ bud" product under the first investigational new drug application or equivalent in Japan, North America or the European Union.

The agreement will expire automatically when there are no remaining intellectual property rights subject to the license. Additionally, Healios may terminate the agreement under certain circumstances, including for material breach and without cause upon advance written notice. We may terminate the agreement if there is an uncured material breach of the agreement by Healios.

Following termination of the agreement, the licenses granted to Healios to develop and commercialize MultiStem in Japan for ischemic stroke, and if the Expansion Option is exercised, for ARDS and the other indication in the orthopedic area, will terminate. Healios will transfer ownership to Athersys of its documents related to the product, the field and the Japan territory, such as regulatory filings, correspondence, approvals and documents; investigator brochures clinical data; and information related to the product. Further, the nonexclusive license to intellectual property developed by Healios during the collaboration shall survive termination and become our confidential information.

RTI

In 2010, we entered into an agreement with RTI to develop and commercialize MAPC technology-based biologic implants for certain orthopedic applications in the bone graft substitutes market on an exclusive basis. Under the terms of our RTI agreement, we received \$5.0 million of license fees in installments during 2010-2012. In accordance with the agreement, we are also eligible to receive an additional \$35.5 million in cash payments upon the successful achievement of certain commercial milestones, though there can be no assurance that such milestones will be achieved, and no significant milestone payments were received as of December 31, 2016. In addition, we receive tiered royalties on worldwide commercial sales of implants using our technologies based on a royalty rate starting in the mid-single digits and increasing into the mid-teens. We began receiving royalties from RTI in 2014. Royalties may be subject to a reduction if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product.

[Table of Contents](#)

The term of the agreement is the longer of (i) five years from the effective date in 2010, (ii) two years after the last sale of a licensed product, (iii) the last to expire of any past, present or future licensed patent, and (iv) the life of trade secrets applicable to the licensed product. Either party can terminate the agreement upon the other party's bankruptcy or for an uncured material breach. RTI can terminate the agreement if our rights to our technology expire such that there is a material effect on the development and commercialization of the licensed products. We can terminate the agreement if RTI has not reached a specified target of sales of the licensed product within five years of the effective date or a specified target of annual sales each year thereafter.

Chugai

In February 2015, we entered into a license agreement with Chugai to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan on an exclusive basis. Under the agreement, Chugai was responsible for the development and commercialization of MultiStem for ischemic stroke in Japan. Under the terms of the agreement, we received an up-front cash payment of \$10 million from Chugai and were entitled to receive a near-term payment of \$7 million tied to the results of our ongoing Phase 2 clinical trial in ischemic stroke, which was not paid by Chugai, thus triggering our right to terminate the agreement. We agreed with Chugai to terminate the agreement in October 2015, when the parties were unable to reach an agreement on a potential modification of the financial terms of the agreement and on development strategy in Japan in light of the 90-day interim results from our Phase 2 clinical study. In connection with the termination, all rights that Chugai had to the program reverted to us, and intellectual property generated through the collaboration is owned by us.

University of Minnesota

In 2003, we acquired the exclusive rights to the MAPC technology originally developed at the University of Minnesota pursuant to a license agreement with the University. Over the convening years, we further developed this technology, including the manufacturing of the cells for use in ongoing clinical trials and ultimately, commercialization. We refer to this lead product as the MultiStem cell therapy platform. We are obligated to pay the University of Minnesota a royalty based on worldwide commercial sales of licensed products if covered by a valid licensed patent, as well as sublicensing fees and fees related to manufactured product proceeds, as defined. The low single-digit royalty and sublicense fee rate may be reduced if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product. The royalty payment obligation and the term of the license agreement expire upon the last to expire licensed patent. Based on our current patent portfolio, and absent any continuations, renewals or extensions of existing patents, the last licensed patent to expire under the license agreement is currently expected to expire in 2029. The license agreement does not have a specific termination date, but the University of Minnesota can terminate the license agreement for an uncured event of default, as defined, or upon our bankruptcy and we can terminate the license agreement at any time.

Bristol-Myers Squibb

In 2000, we entered into a collaboration with Bristol-Myers Squibb to provide cell lines expressing well validated drug targets produced using our RAGE technology for compound screening and development. This initial collaboration was expanded in 2002 and again in 2006, and was in its final phase as amended in 2009. Bristol-Myers Squibb uses the cell lines in its internal drug development programs and, in exchange, we receive license fee and milestone payments and would be entitled to receive royalties on the sale of any approved products. Depending on the use of a cell line by Bristol-Myers Squibb and the progress of drug development programs benefiting from the use of such a cell line, we could receive as much as approximately \$5.5 million per cell line in additional license fees and milestone payments, though we cannot assure you that any further milestones will be achieved or that we will receive any additional milestone payments. As of December 31, 2016, we have received \$9.8 million in license fees since the inception of our collaboration with Bristol-Myers Squibb and an aggregate amount of \$2.7 million in milestone payments, including a \$0.6 million payment received in 2016. Bristol-Myers Squibb still has a few active programs using our cell lines as of December 31, 2016 that could potentially generate revenue for us in the future.

The Bristol-Myers Squibb collaboration does not have a specific termination date, but will terminate when Bristol-Myers Squibb no longer has an obligation to pay us royalties, which obligation generally continues until the later of the expiration of the Bristol-Myers Squibb patent covering an approved product and ten years after commercial sales of that product began. If either party breaches its material obligations and fails to cure that breach within 60 days after notice from the non-breaching party, the non-breaching party may terminate the collaboration.

Manufacturing

We work with third parties to manufacture our MultiStem product candidates in accordance with good manufacturing practices (GMP), and until such time as we are able to manufacture products ourselves in accordance with GMP, we will rely on such third party manufacturers to make our MultiStem product for clinical trials and eventually commercial sales. These third parties may not deliver sufficient quantities of our MultiStem product, manufacture MultiStem product in accordance with specifications, or maintain compliance with applicable government regulations. From time to time, such third party manufacturers, or their material suppliers, may be subject to inspections by the FDA or other regulators, which under certain circumstances could result in production stoppages and interruptions in supply, affecting the initiation, execution and timing of completion of clinical trials or commercial activities. Furthermore, material supply constraints could result in production delays. We attempt to mitigate risks to our product supply by careful planning of our production and raw material requirements with sufficient lead times for ramp-up by third party manufacturers. Additionally, we work with and qualify other third party manufacturers to provide alternative manufacturing capacity, if needed, due to delays or interruptions in supply, but such alternative manufacturers may be subject to similar constraints or issues.

Importantly, we are engaged in process development initiatives intended to increase manufacturing scale, reduce production costs, and enhance process controls and product quality, among other things. These initiatives are being conducted both internally and outsourced to select contractors, and the related investments are meant to enable us to meet potential commercial demand in the event of potential regulatory approval.

Competition

We face significant competition with respect to the various dimensions of our business. With regard to our efforts to develop MultiStem as a novel stem cell therapy, currently, there are a number of companies that are actively developing stem cell products, which encompass a range of different cell types, including embryonic stem cells, umbilical cord stem cells, adult-derived stem cells and processed bone marrow derived cells.

Mesoblast Limited, or Mesoblast, is currently engaged in clinical trials evaluating the safety and efficacy of Revascor, an allogeneic stem cell product based on mesenchymal stem cell precursors that are obtained from healthy consenting donors. These cells also appear to display limited expansion potential and biological plasticity. Additionally, Mesoblast is developing Prochymal, a mesenchymal stem cell product candidate that it acquired from Osiris Therapeutics, Inc.

Other public companies are developing stem-related therapies, including Stem Cells Inc., Vericel Corporation, Tigenix NV, Caladrius Biosciences, Inc., Johnson & Johnson, Celgene Corporation, or Celgene, CRYO-CELL International, Inc., Pluristem Therapeutics, Inc., or Pluristem, and Cytori Therapeutics, Inc., or Cytori. In addition, private companies, such as Gamida Cell Ltd., Ocata Therapeutics Inc., Plureon Corporation, and others, are also developing cell therapy related products or capabilities. Given the magnitude of the potential opportunity for stem cell therapy, we expect competition in this area to intensify in the coming years. In addition, our other earlier-stage programs may face competition, including from larger pharmaceutical and biotechnology companies.

Many of our competitors may have substantially greater financial, technical, sales, marketing, and human resources than we do. These companies may succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products. In addition, our competitors may develop technologies and products that are cheaper, safer or more effective than those being developed by us or that would render our technology obsolete. Furthermore, some of these companies may feel threatened by our activities and attempt to delay or impede our efforts to develop our products or apply our technologies.

Intellectual Property

We rely on a combination of patent applications, patents, trademarks, and contractual provisions to protect our proprietary rights. We believe that to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. Currently, we require our officers, employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, and other advisors to execute confidentiality agreements in connection with their employment, consulting, or advisory relationships with us, where appropriate. We also require our employees, consultants, and advisors that we expect to work on our products to agree to disclose and assign to us all inventions conceived during the work day, developed using our property, or which relate to our business. We currently have over 260 patents for our technologies.

We have a broad patent estate with claims directed to compositions, methods of production, and methods of use of certain non-embryonic stem cells and related technologies. We developed, acquired and exclusively licensed intellectual property covering our cell therapy product candidates and other applications in the field. Our broad intellectual property portfolio consists of nearly 200 issued patents (of which 21 are United States patents) and more than 170 global patent applications around our stem cell technology and MultiStem product platform. This includes twenty United States patents and more than 135 international patents that apply to MAPC and related products, such as MultiStem. The current intellectual property estate, which incorporates additional filings and may broaden over time, could provide coverage for our stem cell product candidates, manufacturing processes and methods of use through 2032 and beyond. Furthermore, an extended period of market exclusivity may apply for certain products (e.g., exclusivity periods for orphan drug designation or biologics).

We have been active in the development, improvement and protection of our intellectual property portfolio through our prosecution efforts, collaborative research efforts, and in-licensing, among other things. From time-to-time, we will also engage in adversarial processes, such as interference or litigation, to protect or advance certain patents or applications. These activities represent an important cost of doing business, and can result in successes and setbacks due to the nature of the processes. For example, over the past several years, we have been involved in several proceedings in the United States with a third party focused on a technology developed after the MAPC technology. In an earlier proceeding, our success resulted in the issuance of a patent. However, in a subsequent proceeding, an interference board ruled that this patent and another application of ours should be cancelled, but this ruling is currently on appeal. Over time, we expect to be involved in similar proceedings with the objective of developing the portfolio to support and protect development and commercialization of our or our licensees' cell therapy products.

We also have established a broad intellectual property portfolio related to our small molecule product candidates, functional genomics, and other technologies with over sixty global patents with claims directed to compositions, methods of making, and methods of using our candidates and technologies, among other claims.

We believe that we have broad freedom to use and commercially develop our technologies and product candidates. However, in the event that we or our collaborators are developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property, a loss in litigation may prevent us from commercializing our products, unless that party grants us rights to use its intellectual property. Further, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if we were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

Research and Development

Our research and development costs, which consist primarily of costs associated with external clinical trial costs, preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property application processes, and laboratory supply and reagent costs, were \$24.8 million in 2016, \$21.3 million in 2015 and \$23.4 million in 2014.

Government Regulation

Any products we may develop and our research and development activities are subject to stringent government regulation in the United States by the FDA and, in many instances, by corresponding foreign and state regulatory agencies. The European Union, or EU, has vested centralized authority in the EMA and Committee on Proprietary Medicinal Products, or CPMP, to standardize review and approval across EU member nations. In Japan, PDMA, a division of the Ministry of Health, Labour and Welfare, or MHLW, regulates the development and commercialization of medical therapies. Recently, Japan's parliament enacted new legislation to promote the safe and accelerated development of treatments using stem cells. The new regenerative medicine law and revised pharmaceutical affairs law define products containing stem cells as regenerative medicine products and allow for the conditional approval of such products if safety has been confirmed in clinical trials, even if their efficacy has not been fully demonstrated. The legislation creates a new, faster pathway for cell therapy product approval, and offers the potential to enable more rapid entry in the Japanese market. The MHLW has been directed to develop and adopt new rules and procedures to implement this legislation.

These regulatory agencies enforce comprehensive statutes, regulations and guidelines governing the drug development process. This process involves several steps. Initially, a company must generate preclinical data to show safety before human testing may be initiated. In the United States, a drug company must submit an IND to the FDA prior to securing authorization for human testing. The IND must contain adequate data on product candidate chemistry, toxicology and metabolism and, where appropriate, animal research testing to support initial safety.

A CTA is the European equivalent of the IND. CTA requirements are issued by each competent authority within the European Union and are enacted by local laws and Directives.

Any of our product candidates will require regulatory approval and compliance with regulations made by United States and foreign government agencies prior to commercialization in such countries. The process of obtaining FDA or foreign regulatory agency approval has historically been extremely costly and time consuming. The FDA and equivalent foreign regulatory authorities (such as the EMA or PMDA) regulate, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale, and distribution of biologics and new drugs.

The standard process required by the FDA before a pharmaceutical agent may be marketed in the United States includes:

- preclinical tests in animals that demonstrate a reasonable likelihood of safety and effectiveness (if possible) in human patients;

[Table of Contents](#)

- submission to the FDA of an IND, which must become effective before clinical trials in humans can commence. If Phase 1 clinical trials are to be conducted initially outside the United States, a different regulatory filing is required, depending on the location of the trial;
- adequate and well controlled human clinical trials to establish the safety and efficacy of the drug or biologic product for the intended disease indication;
- for drugs, (including biologics) submission of a New Drug Application, or NDA, or a BLA with the FDA; and
- FDA approval of the NDA or BLA before any commercial sale or shipment of the drug.

Preclinical studies can take several years to complete, and there is no guarantee that an IND based on those studies will become effective to permit clinical trials to begin. The clinical development phase generally takes ten to fifteen years, or longer, to complete (i.e., from the initiation of Phase 1 through completion of Phase 3 studies), and such sequential studies may overlap or be combined. After successful completion of clinical trials for a new drug or biologic product, FDA approval of the NDA or BLA must be obtained. This process requires substantial time and effort and there is no assurance that the FDA will accept the NDA or BLA for filing and, even if filed, that the FDA will grant approval. In the past, the FDA's approval of an NDA or BLA has taken, on average, one to two years, but in some instances may take substantially longer. If questions regarding safety or efficacy arise, additional studies may be required, followed by a resubmission of the NDA or BLA. Review and approval of an NDA or BLA can take up to several years. The FDA and other Regulatory agencies such as the EMA and PMDA have regulations that allow for faster approval paths and review cycles that may reduce clinical development phase completion to between five and seven years to commercialization. Such regulations include but are not limited to accelerated/conditional approval paths and review cycles of between six to ten months (priority/accelerated review cycles). However, there are specific criteria that must be met to qualify for these paths, such as high unmet medical need, orphan designation, fast track, exceptional circumstances and breakthrough designation.

In addition to obtaining FDA approval for each product being sold in the United States, each drug manufacturing facility must be inspected and approved by the FDA. All manufacturing establishments are subject to inspections by the FDA and by other federal, state, and local agencies, and must comply with good manufacturing practices, or GMP, requirements. We do not currently have any GMP manufacturing capabilities, and will rely on contract manufacturers to produce material for any clinical trials that we conduct.

We must also obtain regulatory approval in other countries in which we intend to market any drug. The requirements governing conduct of clinical trials, product licensing, pricing, and reimbursement vary widely from country to country. FDA approval does not ensure regulatory approval in other countries. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In some countries, the sale price of the drug must also be approved. The pricing review period often begins after market approval is granted. Even if a foreign regulatory authority approves a drug product, it may not approve satisfactory prices for the product.

In addition to regulations enforced by the FDA and international regulatory agencies, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other present and potential future federal, state, or local regulations. Our research and development involves the controlled use of hazardous materials, chemicals, biological materials, and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials currently comply in all material respects with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our available resources.

Employees

We believe that our success will be based on, among other things, the quality of our clinical programs, our ability to invent and develop superior and innovative technologies and products, and our ability to attract and retain capable management and other personnel. We have assembled a high quality team of scientists, clinical development managers, and executives with significant experience in the biotechnology and pharmaceutical industries.

As of December 31, 2016, we employed 60 full-time employees, including 15 with Ph.D. degrees. In addition to our employees, we also use the service and support of outside consultants and advisors. None of our employees is represented by a union, and we believe relationships with our employees are good.

Available Information

We use the Investors section of our web site, www.athersys.com, as a channel for routine distribution of important information, including news releases, analyst presentations and financial information. We post filings as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC, including our annual, quarterly, and current reports on Forms 10-K, 10-Q, and 8-K; our proxy statements; and any amendments to those reports or statements. All such postings and filings are available on the Investors section of our web site free of charge. In addition, this web site allows investors and other interested persons to sign up to automatically receive e-mail alerts when we post news releases and financial information on our web site. The SEC also maintains a web site, www.sec.gov, that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The content on any web site referred to in this annual report on Form 10-K is not incorporated by reference into this annual report unless expressly noted.

ITEM 1A. RISK FACTORS

The statements in this section, as well as statements described elsewhere in this annual report, or in other SEC filings, describe risks that could materially and adversely affect our business, financial condition and results of operations, which could also cause the trading price of our equity securities to decline. These risks are not the only risks that we face. Our business, financial condition and results of operations could also be affected by additional factors that are not presently known to us or that we currently consider to be immaterial to our operations.

We have incurred losses since inception and we expect to incur significant net losses in the foreseeable future and may never become profitable.

Since our inception in 1995, we incurred significant losses and negative cash flows from operations. We incurred net losses of \$15 million in 2016, \$16 million in 2015 and \$22 million in 2014. As of December 31, 2016, we had an accumulated deficit of \$318 million and anticipate incurring additional losses for at least the next several years. We expect to spend significant resources over the next several years to enhance our technologies and to fund research and development of our pipeline of potential products. To date, substantially all of Athersys' revenue has been derived from corporate collaborations, license agreements and government grants. In order to achieve profitability, we must develop products and technologies that can be commercialized by us or through our existing or future collaborations. Our ability to generate revenues and become profitable will depend on our ability, alone or with potential collaborators, to timely, efficiently and successfully complete the development of our product candidates. We have never earned revenue from selling a product and we may never do so, as none of our product candidates have been approved for sale, since they are currently being tested in humans and animal studies. We cannot assure you that we will ever earn sales revenue or that we will ever become profitable. If we sustain losses over an extended period of time, we may be unable to continue our business.

We will need substantial additional funding to develop our products and for our future operations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development activities or may be unable to continue our business.

The development of our product candidates will require a commitment of substantial funds to conduct the costly and time-consuming research, which may include preclinical and clinical testing, necessary to obtain regulatory approvals and bring our products to market. Net cash used in our operations was \$11 million in 2016, \$14 million in 2015 and \$26 million in 2014.

At December 31, 2016, we had \$15 million of cash and cash equivalents, and in February 2017, we added \$20.9 million to our cash position through the issuance of common stock in a public offering. However, we will need substantially more to advance our product candidates through development. Furthermore, we will need to add additional capital to fund our operations through the completion of our current clinical trials. Our future capital requirements will depend on many factors, including:

- our ability to raise capital to fund our operations;
- the progress, scope, costs, and results of our clinical and preclinical testing of any current or future product candidates;
- the possibility of delays in, adverse events of, and excessive costs of the development process;
- the cost of manufacturing our product candidates;
- the cost of prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the time and cost involved in obtaining regulatory approvals;
- expenses related to complying with good manufacturing practices, or GMP, of therapeutic product candidates;
- costs of financing or acquiring additional capital equipment and development technologies;
- competing technological and market developments;

- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements;
- the amount and timing of payments or equity investments that we receive from collaborators or changes in or terminations of future or existing collaboration and licensing arrangements and the timing and amount of expenses we incur to supporting these collaborations and license agreements;
- costs associated with the integration of any new operation, including costs relating to future mergers and acquisitions with companies that have complementary capabilities;
- expenses related to the establishment of sales and marketing capabilities for products awaiting approval or products that have been approved;
- the level of our sales and marketing expenses; and
- our ability to introduce and sell new products.

The extent to which we utilize our existing equity purchase agreement with Aspire Capital Fund, LLC, or Aspire Capital, as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the purchase agreement on any given day and during the term of the agreement is limited. Additionally, we and Aspire Capital may not affect any sales of shares of our common stock under the purchase agreement during the continuance of an event of default. Even if we are able to access the \$26 million available under the purchase agreement as of December 31, 2016, we will still need additional capital to fully implement our business, operating and development plans.

We have secured capital historically from grant revenues, collaboration proceeds, and debt and equity offerings. We will need to secure substantial additional capital to fund our future operations. We cannot be certain that additional capital will be available on acceptable terms or at all. In recent years, it has been difficult for companies to raise capital due to a variety of factors, which may or may not continue. To the extent we raise additional capital through the sale of equity securities, including to Aspire Capital, the ownership position of our existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock. Fluctuating interest rates could also increase the costs of any debt financing we may obtain.

Failure to successfully address ongoing liquidity requirements will have a material adverse effect on our business. If we are unable to obtain additional capital on acceptable terms when needed, we may be required to take actions that harm our business and our ability to achieve cash flow in the future, including possibly the surrender of our rights to some technologies or product opportunities, delaying our clinical trials or curtailing or ceasing operations.

We are heavily dependent on the successful development and commercialization of MultiStem products, and if we encounter delays or difficulties in the development of these product candidate, our business could be harmed.

Our success is heavily dependent upon the successful development of MultiStem products for certain diseases and conditions involving acute or ischemic injury or immune system dysfunction. Our business could be materially harmed if we encounter difficulties in the development of this product candidate, such as:

- delays in the ability to manufacture the product in quantities or in a form that is suitable for any required preclinical studies or clinical trials;
- an inability to produce the product at an appropriate cost or to scale for commercialization;
- delays in the design, enrollment, implementation or completion of required preclinical studies and clinical trials;
- an inability to follow our current development strategy for obtaining regulatory approval from regulatory authorities because of changes in the regulatory approval process;
- less than desired or complete lack of efficacy or safety in preclinical studies or clinical trials; and
- intellectual property constraints that prevent us from making, using or commercializing the product candidate.

Our product candidates are currently in the development stage and we have no therapeutic products approved for sale. If we are unable to develop, obtain regulatory approval or market any of our product candidates, our financial condition will be negatively affected, and we may have to curtail or cease our operations.

Many factors, known and unknown, can adversely affect clinical trials and the ability to evaluate a product's efficacy. During the course of treatment, patients can die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. Even if unrelated to our product, certain events can nevertheless adversely impact our clinical trials. As a result, our ability to ultimately develop and market the products and obtain revenues would suffer.

Even promising results in preclinical studies and initial clinical trials do not ensure successful results in later clinical trials, which test broader human use of our products. Many companies in our industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials.

We are in the early stage of product development, and we are dependent on the application of our technologies to discover or develop therapeutic product candidates. We currently do not sell any approved therapeutic products and do not expect to have any products commercially available for several years, if at all. You must evaluate us in light of the uncertainties and complexities affecting an early stage biotechnology company. Our product candidates require additional research and development, preclinical testing, clinical testing and regulatory review and/or approvals or clearances before marketing. To date, no one to our knowledge has commercialized any therapeutic products using our technologies and we might never commercialize any product using our technologies and strategy. In addition, we may not succeed in developing new product candidates as an alternative to our existing portfolio of product candidates. If our current product candidates are delayed or fail, or we fail to successfully develop and commercialize new product candidates, our financial condition may be negatively affected, and we may have to curtail or cease our operations.

We may not successfully maintain our existing collaborative and licensing arrangements, or establish new ones, which could adversely affect our ability to develop and commercialize our product candidates.

A key element of our business strategy is to commercialize some of our product candidates through collaborations with other companies. Our strategy includes establishing collaborations and licensing agreements with one or more pharmaceutical, biotechnology or device companies, preferably after we have advanced product candidates through the initial stages of clinical development. However, we may not be able to establish or maintain such licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

Our agreements with our collaborators and licensees may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply, or commercialization of certain product candidates, or could require or result in litigation or arbitration. Moreover, disagreements could arise with our collaborators over rights to intellectual property or our rights to share in any of the future revenues of products developed by our collaborators. These kinds of disagreements could result in costly and time-consuming litigation. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators.

Currently, our material collaborations and licensing arrangements are our collaborations with Healios to develop and commercialize MultiStem cell therapy for the treatment of ischemic stroke in Japan and potentially other conditions, and RTI to develop and commercialize MAPC technology-based biologic implants for certain orthopedic applications in the bone graft substitutes market, and our license agreements with third parties pursuant to which we license certain aspects of our technologies. These arrangements may not have specific termination dates; rather, each arrangement terminates upon the occurrence of certain events.

If our collaborators do not devote sufficient time and resources to successfully carry out their contracted duties or meet expected deadlines, we may not be able to advance our product candidates in a timely manner or at all.

Our success depends on the performance by our collaborators of their responsibilities under our collaboration arrangements. Some potential collaborators may not perform their obligations in a timely fashion or in a manner satisfactory to us. Typically, we cannot control the amount of resources or time our collaborators may devote to our programs or potential products that may be developed in collaboration with us. We are currently involved in multiple research and development collaborations with academic and research institutions. These collaborators frequently depend on outside sources of funding to conduct or complete research and development, such as grants or other awards. In addition, our academic collaborators may depend on graduate students, medical students, or research assistants to conduct certain work, and such individuals may not be fully trained or experienced in certain areas, or they may elect to discontinue their participation in a particular research program, creating an inability to complete ongoing research in a timely and efficient manner. As a result of these uncertainties, we are unable to control the precise timing and execution of any experiments that may be conducted.

Additionally, our current or future corporate collaborators will retain the ability to pursue other research, product development or commercial opportunities that may be directly competitive with our programs. If these collaborators elect to prioritize or pursue other programs in lieu of ours, we may not be able to advance product development programs in an efficient or effective manner, if at all. If a collaborator is pursuing a competitive program and encounters unexpected financial or capability limitations, they may be motivated to reduce the priority placed on our programs or delay certain activities related to our programs or be unwilling to properly fund their share of the development expenses for our programs. Any of these developments could harm our product and technology development efforts, which could seriously harm our business.

We may experience delays in clinical trials and regulatory approval relating to our products that could adversely affect our financial results and our commercial prospects for our pharmaceutical or stem cell products.

In addition to the regulatory requirements for our pharmaceutical programs, we will also require regulatory approvals for each distinct application of our stem cell product. In each case, we will be required to conduct clinical trials to demonstrate safety and efficacy of MultiStem, or various products that incorporate or use MultiStem. For product candidates that advance to clinical testing, we cannot be certain that we or a collaborator will successfully complete the clinical trials necessary to receive regulatory product approvals. This process is lengthy and expensive.

We intend to seek approval for our product candidates through the FDA approval process in the United States, and through other regulatory agencies outside the United States. To obtain regulatory approvals, we must, among other requirements, complete clinical trials showing that our products are safe and effective for a particular indication. Under the approval process, we must submit clinical and non-clinical data to demonstrate the product is safe and effective. For example, we must be able to provide data and information, which may include extended pharmacology, toxicology, reproductive toxicology, bioavailability and genotoxicity studies, to establish suitability for late stage clinical trials.

All of our product candidates are in clinical development. As these programs progress through clinical development, or complete additional non-clinical testing, an indication of a lack of safety or lack of efficacy may result in the early termination of an ongoing study, or may cause us or any of our collaborators to forego further development of a particular product candidate or program. The FDA or other regulatory agencies may require extensive clinical trials or other testing prior to granting approval, which could be costly and time consuming to conduct. Any of these developments could hinder, and potentially prohibit, our ability to commercialize our product candidates. We cannot assure you that clinical trials will demonstrate that our products are safe and effective.

Additionally, we may not be able to find acceptable patients or may experience delays in enrolling patients for our currently planned or any future clinical trials. The FDA, international regulatory agencies or we may suspend our clinical trials at any time if it is believed that we are exposing the subjects participating in the trials to unacceptable health risks. The regulatory authorities or institutional review boards and/or institutional biosafety committees at the medical institutions and healthcare facilities where we seek to sponsor clinical trials may not permit a trial to proceed or may suspend any trial indefinitely if they find deficiencies in the conduct of the trials.

Product development costs to us and our potential collaborators will increase if we have delays in testing or approvals or if we need to perform more or larger clinical trials than planned. We expect to continue to rely on third-party clinical investigators at medical institutions and healthcare facilities to conduct our clinical trials, and, as a result, we may face additional delaying factors outside our control. Significant delays may adversely affect our financial results and the commercial prospects for our product candidates and delay our ability to become profitable.

The results seen in animal testing of our product candidates may not be replicated in humans.

Safety and efficacy seen in preclinical testing of our product candidates in animals may not be seen when our product candidates undergo clinical testing in humans. Preclinical studies and Phase 1 clinical trials are not primarily designed to test the efficacy of a product candidate in humans, but rather to:

- test short-term safety and tolerability;
- study the absorption, distribution, metabolism and elimination of the product candidate;
- study the biochemical and physiological effects of the product candidate and the mechanisms of the drug action and the relationship between drug levels and effect; and
- understand the product candidate's side effects at various doses and schedules.

Success in preclinical studies or completed clinical trials does not ensure that later studies or trials, including continuing non-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. The rate of failure in drug development is quite high, and many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Product candidates may fail to show desired safety and efficacy in larger and more diverse patient populations in later stage clinical trials, despite having progressed through early stage trials. Negative or inconclusive results from any of our ongoing preclinical studies or clinical trials could result in delays, modifications, or abandonment of ongoing or future clinical trials and the termination of our development of a product candidate. Additionally, even if we are able to successfully complete late stage clinical trials, the regulatory authorities still may not approve our product candidates.

Even if we obtain regulatory approval of any of our product candidates, the approved products may be subject to post-approval studies and will remain subject to ongoing regulatory requirements. If we fail to comply, or if concerns are identified in subsequent studies, our approval could be withdrawn and our product sales could be suspended.

If we are successful at obtaining regulatory approval for MultiStem or any of our other product candidates, regulatory agencies in the United States and other countries where a product will be sold may require extensive additional clinical trials or post-approval clinical studies that are expensive and time consuming to conduct. In particular, therapeutic products administered for the treatment of persistent or chronic conditions, such as obesity, are likely to require extensive follow-up studies and close monitoring of patients after regulatory approval has been granted, for any signs of adverse effects that occur over a long period of time. These studies may be expensive and time consuming to conduct and may reveal side effects or other harmful effects in patients that use our therapeutic products after they are on the market, which may result in the limitation or withdrawal of our drugs from the market. Alternatively, we may not be able to conduct such additional trials, which might force us to abandon our efforts to develop or commercialize certain product candidates. Even if post-approval studies are not requested or required, after our products are approved and on the market, there might be safety issues that emerge over time that require a change in product labeling or that require withdrawal of the product from the market, which would cause our revenue to decline.

Additionally, any products that we may successfully develop will be subject to ongoing regulatory requirements after they are approved. These requirements will govern the manufacturing, packaging, marketing, distribution, and use of our products. If we fail to comply with such regulatory requirements, approval for our products may be withdrawn, and product sales may be suspended. We may not be able to regain compliance, or we may only be able to regain compliance after a lengthy delay, significant expense, lost revenues and damage to our reputation.

If we inadvertently violate the guidelines pertaining to promotion and advertising of our clinical candidates or approved products, we may be subject to disciplinary action by the FDA's Division of Drug Marketing, Advertising, and Communications or other regulatory bodies.

The FDA's Division of Drug Marketing, Advertising, and Communications, or DDMAC, is responsible for reviewing prescription drug advertising and promotional labeling to ensure that the information contained in these materials is not false or misleading. There are specific disclosure requirements and the applicable regulations mandate that advertisements cannot be false or misleading or omit material facts about the product. Prescription drug promotional materials must present a fair balance between the drug's effectiveness and the risks associated with its use. Most warning letters from DDMAC cite inadequate disclosure of risk information.

DDMAC prioritizes its actions based on the degree of risk to the public health, and often focuses on newly introduced drugs and those associated with significant health risks. There are two types of letters that DDMAC typically sends to companies which violate its drug advertising and promotional guidelines: notice of violation letters, or untitled letters, and warning letters. In the case of an untitled letter, DDMAC typically alerts the drug company of the violation and issues a directive to refrain from future violations, but does not typically demand other corrective action. A warning letter is typically issued in cases that are more serious or where the company is a repeat offender. Although we have not received any such letters from DDMAC, we may inadvertently violate DDMAC's guidelines in the future and be subject to a DDMAC untitled letter or warning letter, which may have a negative impact on our business.

We may rely on third parties to manufacture our MultiStem product candidate.

Our current business strategy relies on third parties to manufacture our MultiStem product candidates in accordance with good manufacturing practices established by the FDA or similar regulations in other countries. These third parties may not deliver sufficient quantities of our MultiStem product, manufacture MultiStem product in accordance with specifications, or comply with applicable government regulations. From time to time, such third party manufacturers, or their material suppliers, may experience production delays, stoppages or interruptions in supply, which may affect the initiation, execution and timing of completion of clinical trials or commercial activities. Additionally, if the manufactured product fails to perform as specified, our business and reputation could be severely impacted.

If and until we are able to manufacture our products ourselves, we expect to enter into additional manufacturing agreements for the production of our products. If any manufacturing agreement is terminated or any third party collaborator experiences a significant problem that could result in a delay or interruption in the supply of product materials to us, there are few contract manufacturers that currently have the capability to produce our MultiStem product on acceptable terms, or on a timely and cost-effective basis. We cannot assure you that manufacturers on whom we will depend will be able to successfully produce our MultiStem product on acceptable terms, or on a timely or cost-effective basis. We cannot assure you that manufacturers will be able to manufacture our products in accordance with our product specifications or will meet regulatory or other requirements. We must have sufficient and acceptable quantities of our product materials to conduct our clinical trials and ultimately to market our products, if and when such products have been approved for marketing. If we are unable to obtain sufficient and acceptable quantities of our product, we may be required to delay the clinical testing and marketing of our products.

If we do not comply with applicable regulatory requirements in the manufacture and distribution of our product candidates, we may incur penalties that may inhibit our ability to commercialize our products and adversely affect our revenue.

Our failure or the failure of our potential collaborators or third party manufacturers to comply with applicable FDA or other regulatory requirements including manufacturing, quality control, labeling, safety surveillance, promoting and reporting may result in criminal prosecution, civil penalties, recall or seizure of our products, total or partial suspension of production or an injunction, as well as other regulatory action against our product candidates or us. Discovery of previously unknown problems with a product, supplier, manufacturer or facility may result in restrictions on the sale of our products, including a withdrawal of such products from the market. The occurrence of any of these events would negatively impact our business and results of operations.

If we are unable to attract and retain key personnel and advisors, it may adversely affect our ability to obtain financing, pursue collaborations or develop our product candidates.

We are highly dependent on our executive officers Gil Van Bokkelen, Ph.D., our Chief Executive Officer, William Lehmann, J.D., M.B.A., President and Chief Operating Officer, John Harrington, Ph.D., Chief Scientific Officer and Executive Vice President, and Laura Campbell, CPA, Senior Vice President of Finance, as well as other personnel.

These individuals are integral to the development and integration of our technologies and to our present and future scientific collaborations, including managing the complex research processes and the product development and potential commercialization processes. Given their leadership, extensive technical, scientific and financial expertise and management and operational experience, these individuals would be difficult to replace. Consequently, the loss of services of one or more of these named individuals could result in product development delays or the failure of our collaborations with current and future collaborators, which, in turn, may hurt our ability to develop and commercialize products and generate revenues.

Our future success depends on our ability to attract, retain and motivate highly qualified management and scientific, development and commercial personnel and advisors. If we are unable to attract and retain key personnel and advisors, it may negatively affect our ability to successfully develop, test and commercialize our product candidates.

Our ability to compete may decline if we are not successful in adequately protecting our patented and other proprietary technologies.

Our success depends in part on our ability to obtain and maintain intellectual property that protects our technologies and our products. Patent positions may be highly uncertain and may involve complex legal and factual questions, including the ability to establish patentability of compounds and methods for using them for which we seek patent protection. We cannot predict the breadth of claims that will ultimately be allowed in our patent applications, if any, including those we have in-licensed or the extent to which we may enforce these claims against our competitors. We have filed multiple patent applications that seek to protect the composition of matter and method of use related to our programs. In addition, we are prosecuting numerous distinct patent families directed to composition, methods of production, and methods of use of MultiStem and related technologies. If we are unsuccessful in obtaining and maintaining these patents related to products and technologies, we may ultimately be unable to commercialize products that we are developing or may elect to develop in the future.

The degree of future protection for our proprietary rights is therefore highly uncertain and we cannot assure you that:

- we were the first to file patent applications or to invent the subject matter claimed in patent applications relating to the technologies or product candidates upon which we rely;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- others did not publicly disclose our claimed technology before we conceived the subject matter included in any of our patent applications;
- any of our pending or future patent applications will result in issued patents;
- any of our patent applications will not result in interferences or disputes with third parties regarding priority of invention;
- any patents that may be issued to us, our collaborators or our licensors will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our ability to do business; or
- new proprietary technologies from third parties, including existing licensors, will be available for licensing to us on reasonable commercial terms, if at all.

In addition, patent law outside the United States is uncertain and in many countries intellectual property laws are undergoing review and revision. The laws of some countries do not protect intellectual property rights to the same extent as domestic laws. It may be necessary or useful for us to participate in opposition proceedings to determine the validity of our competitors' patents or to defend the validity of any of our or our licensor's future patents, which could result in substantial costs and would divert our efforts and attention from other aspects of our business. With respect to certain of our inventions, we decided not to pursue patent protection outside the United States, both because we do not believe it is cost effective and because of confidentiality concerns. Accordingly, our international competitors could develop and receive foreign patent protection for gene sequences and functions for which we are seeking United States patent protection, enabling them to sell products that we developed.

Technologies licensed to us by others, or in-licensed technologies, are important to our business. The scope of our rights under our licenses may be subject to dispute by our licensors or third parties. Our rights to use these technologies and to practice the inventions claimed in the licensed patents are subject to our licensors abiding by the terms of those licenses and not terminating them. In particular, we depend on certain technologies relating to our MultiStem technology licensed from the University of Minnesota, and the termination of this license could result in our loss of some of the rights that enable us to utilize this technology, and our ability to develop products based on MultiStem could be seriously hampered.

In addition, we may in the future acquire rights to additional technologies by licensing such rights from existing licensors or from third parties. Such in-licenses may be costly. Also, we generally do not control the patent prosecution, maintenance or enforcement of in-licensed technologies. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we do over our internally developed technologies. Moreover, some of our academic institution licensors, collaborators and scientific advisors have rights to publish data and information to which we have rights. If we cannot maintain the confidentiality of our technologies and other confidential information in connection with our collaborations, our ability to protect our proprietary information or obtain patent protection in the future may be impaired, which could have a significant adverse effect on our business, financial condition and results of operations.

We may not have adequate protection for our unpatented proprietary information, which could adversely affect our competitive position.

In addition to patents, we will substantially rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. However, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. To protect our trade secrets, we may enter into confidentiality agreements with employees, consultants and potential collaborators. However, these agreements may not provide meaningful protection of our trade secrets or adequate remedies in the event of unauthorized use or disclosure of such information. Likewise, our trade secrets or know-how may become known through other means or be independently discovered by our competitors. Any of these events could prevent us from developing or commercializing our product candidates.

We may be sued for product liability, which could adversely affect our business.

Because our business strategy involves the development and sale by either us or our collaborators of commercial products, we may be sued for product liability. We may be held liable if any product we develop and commercialize, or any product our collaborators commercialize that incorporates any of our technology, causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. In addition, the safety studies we must perform and the regulatory approvals required to commercialize our pharmaceutical products, will not protect us from any such liability.

We carry product liability insurance that includes coverage for human clinical trials. Currently, we insure a total limit of \$15 million per occurrence, \$15 million annual aggregate coverage for both our products liability policy and our clinical trials protection. This limit is comprised of both primary and excess coverage. We also intend to seek product liability insurance for any approved products that we may develop or acquire. However, in the event there are product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any of our approved products. If such insurance is insufficient to protect us, our results of operations will suffer. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage.

Many potential competitors, including those who have greater resources and experience than we do, may develop products or technologies that make ours obsolete or noncompetitive.

We face significant competition with respect to our product candidates. With regard to our efforts to develop MultiStem as a novel stem cell therapy, currently, there are a number of companies that are actively developing stem cell products, which encompass a range of different cell types, including embryonic stem cells, adult-derived stem cells, and processed bone marrow derived cells. Our future success will depend on our ability to maintain a competitive position with respect to technological advances. Technological developments by others may result in our MultiStem product platform and technologies, as well as our pharmaceutical formulations, becoming obsolete.

We are subject to significant competition from pharmaceutical, biotechnology and diagnostic companies, academic and research institutions, and government or other publicly funded agencies that are pursuing or may pursue the development of therapeutic products and technologies that are substantially similar to our proposed therapeutic products and technologies, or that otherwise address the indications we are pursuing. Our most significant competitors include major pharmaceutical companies such as Pfizer, Roche, Johnson & Johnson, Sanofi and GlaxoSmithKline, as well as smaller biotechnology or biopharmaceutical companies such as Celgene, Mesoblast, Aastrom, Stem Cells Inc., Cytori, Pluristem, Arena Pharmaceuticals and Vivus. Most of our current and potential competitors have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources, and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the United States and internationally.

Many of these companies have substantially greater capital resources, research and development resources and experience, manufacturing capabilities, regulatory expertise, sales and marketing resources, established relationships with consumer products companies and production facilities.

Universities and public and private research institutions are also potential competitors. While these organizations primarily have educational objectives, they may develop proprietary technologies related to stem cells or secure patent protection that we may need for the development of our technologies and products. We may attempt to license these proprietary technologies, but these licenses may not be available to us on acceptable terms, if at all. Our competitors, either alone or with their collaborative partners, may succeed in developing technologies or products that are more effective, safer, more affordable or more easily commercialized than ours, and our competitors may obtain intellectual property protection or commercialize products sooner than we do. Developments by others may render our product candidates or our technologies obsolete.

Our current product discovery and development collaborators are not prohibited from entering into research and development collaboration agreements with third parties in any product field. Our failure to compete effectively would have a significant adverse effect on our business, financial condition and results of operations.

The availability, manner, and amount of reimbursement for our product candidates from government and private payers are uncertain, and our inability to obtain adequate reimbursement for any products could severely limit our product sales.

We expect that many of the patients who seek treatment with any of our products that are approved for marketing will be eligible for Medicare benefits. Other patients may be covered by private health plans. If we are unable to obtain or retain adequate levels of reimbursement from Medicare or from private health plans, our ability to sell our products will be severely limited. The application of existing Medicare regulations and interpretive coverage and payment determinations to newly approved products is uncertain and those regulations and interpretive determinations are subject to change. Medicare may change its reimbursement methodology that reduces the Medicare reimbursement rates for many drugs, which may adversely affect reimbursement for any products we may develop. Medicare regulations and interpretive determinations also may determine who may be reimbursed for certain services, and may limit the pool of patients our product candidates are being developed to serve.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. We anticipate continuing debate in 2017 and in the foreseeable future over the research and development, marketing, pricing and reimbursement for health care products and services, including those that would affect our current product candidates. For example, Federal, state and foreign governments continue to propose legislation designed to contain or reduce health care costs. Among other developments, the new United States presidential administration has identified repealing and replacing the Patient Protection and Affordable Care Act (ACA), enacted in 2010 as a priority. The timing and method of repeal and replacement, should it occur, is uncertain but changes could include the number of patient lives covered, the type of insurance coverage available and patient eligibility. Legislation and regulations affecting the pricing of products like our potential products may change further or be adopted before any of our potential products are approved for marketing. Cost control initiatives by governments or third-party payers could decrease the price that we receive for any one or all of our potential products or increase patient coinsurance to a level that make our products under development become unaffordable. In addition, government and private health plans persistently challenge the price and cost-effectiveness of therapeutic products. Accordingly, these third parties may ultimately not consider any or all of our products under development to be cost effective, which could result in products not being covered under their health plans or covered only at a lower price. Any of these initiatives or developments could prevent us from successfully marketing and selling any of our products that are approved for commercialization.

Public perception of ethical and social issues surrounding the use of adult-derived stem cell technology may limit or discourage the use of our technologies, which may reduce the demand for our therapeutic products and technologies and reduce our revenues.

Our success will depend in part upon our ability to develop therapeutic products incorporating or discovered through our adult-derived stem cell technology. For social, ethical, or other reasons, governmental authorities in the United States and other countries may call for limits on, or regulation of the use of, adult-derived stem cell technologies. Although we do not use the more controversial stem cells derived from embryos or fetuses, claims that adult-derived stem cell technologies are ineffective, unethical or pose a danger to the environment may influence public attitudes. The subject of stem cell technologies in general has received negative publicity and aroused public debate in the United States and some other countries. Ethical and other concerns about our adult-derived stem cell technology could materially hurt the market acceptance of our therapeutic products and technologies, resulting in diminished sales and use of any products we are able to develop using adult-derived stem cells.

Even if we or our collaborators receive regulatory approval for our products, those products may never be commercially successful.

Even if we develop pharmaceuticals or MultiStem-related products that obtain the necessary regulatory approval, and we have access to the necessary manufacturing, sales, marketing and distribution capabilities that we need, our success depends to a significant degree upon the commercial success of those products. If these products fail to achieve or subsequently maintain market acceptance or commercial viability, our business would be significantly harmed because our future royalty revenue or other revenue would be dependent upon sales of these products. Many factors may affect the market acceptance and commercial success of any potential products that we may discover, including:

- health concerns, whether actual or perceived, or unfavorable publicity regarding our obesity drugs, stem cell products or those of our competitors;
- the timing of market entry as compared to competitive products;
- the rate of adoption of products by our collaborators and other companies in the industry;
- any product labeling that may be required by the FDA or other United States or foreign regulatory agencies for our products or competing or comparable products;
- convenience and ease of administration;
- pricing;
- perceived efficacy and side effects;
- marketing;
- availability of alternative treatments;
- levels of reimbursement and insurance coverage; and
- activities by our competitors.

If we are unable to create and maintain sales, marketing and distribution capabilities or enter into agreements with third parties to perform those functions, we will not be able to commercialize our product candidates.

We currently have no sales, marketing or distribution capabilities. Therefore, to commercialize our product candidates, if and when such products have been approved and are ready for marketing, we expect to collaborate with third parties to perform these functions. We will either need to share the value generated from the sale of any products and/or pay a fee to the contract sales organization. If we establish any such relationships, we will be dependent upon the capabilities of our collaborators or contract service providers to effectively market, sell, and distribute our product. If they are ineffective at selling and distributing our product, or if they choose to emphasize other products over ours, we may not achieve the level of product sales revenues that we would like. If conflicts arise, we may not be able to resolve them easily or effectively, and we may suffer financially as a result. If we cannot rely on the sales, marketing and distribution capabilities of our collaborators or of contract service providers, we may be forced to establish our own capabilities. We have no experience in developing, training or managing a sales force and will incur substantial additional expenses if we decide to market any of our future products directly. Developing a marketing and sales force is also time consuming and could delay launch of our future products. In addition, we will compete with many companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete successfully against these companies.

We will use hazardous and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our products and processes will involve the controlled storage, use and disposal of certain hazardous and biological materials and waste products. We and our suppliers and other collaborators are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of any insurance we may obtain and exceed our financial resources. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs to comply with current or future environmental laws and regulations.

Disputes concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and extremely costly and could delay our research and development efforts.

Our commercial success, if any, will be significantly harmed if we infringe the patent rights of third parties or if we breach any license or other agreements that we entered into with regard to our technology or business.

We are aware of other companies and academic institutions that have been performing research in the areas of adult-derived stem cells. In particular, other companies and academic institutions have announced that they have identified nonembryonic stem cells isolated from bone marrow or other tissues that have the ability to form a range of cell types, or display the property of pluripotency. To the extent any of these companies or academic institutions currently have, or obtain in the future, broad patent claims, such patents could block our ability to use various aspects of our discovery and development process and might prevent us from developing or commercializing newly discovered applications of our MultiStem technology, or otherwise conducting our business. In addition, it is possible that some of the pharmaceutical product candidates we are developing may not be patentable or may be covered by intellectual property of third parties. For example, over the past several years, we have been involved in several proceedings in the United States with a third party focused on a technology developed after the MAPC technology. In an earlier proceeding, our success resulted in the issuance of a patent. However, in a more recent proceeding, an interference board ruled that this patent and another application of ours should be cancelled, but this ruling is currently on appeal. Over time, we expect to be involved in similar proceedings with the objective of developing the portfolio to support and protect development and commercialization of our or our licensees' cell therapy products.

We are not currently a party to any litigation with regard to our patent or trademark positions. However, the life sciences and other technology industries are characterized by extensive litigation regarding patents and other intellectual property rights. Many life sciences and other technology companies have employed intellectual property litigation as a way to gain a competitive advantage. To the extent we are involved in litigation, interference proceedings, oppositions, reexamination, protest or other potentially adverse intellectual property proceedings as a result of alleged infringement by us of the rights of others or as a result of priority of invention disputes with third parties, we might have to spend significant amounts of money, time and effort defending our position and we may not be successful. In addition, any claims relating to the infringement of third-party proprietary rights or proprietary determinations, even if not meritorious, could result in costly litigation, lengthy governmental proceedings, divert management's attention and resources, or require us to enter into royalty or license agreements that are not advantageous to us. If we do not have the financial resources to support such litigation or appeals, we may forfeit or lose certain commercial rights. Even if we have the financial resources to continue such litigation or appeals, we may lose. In the event that we lose, we may be forced to pay very substantial damages; we may have to obtain costly license rights, which may not be available to us on acceptable terms, if at all; or we may be prohibited from selling products that are found to infringe the patent rights of others.

Should any person have filed patent applications or obtained patents that claim inventions also claimed by us, we may have to participate in an interference proceeding declared by the relevant patent regulatory agency to determine priority of invention and, thus, the right to a patent for these inventions in the United States. Such a proceeding could result in substantial cost to us even if the outcome is favorable. Even if successful on priority grounds, an interference action may result in loss of claims based on patentability grounds raised in the interference action. Litigation, interference proceedings or other proceedings could divert management's time and efforts. Even unsuccessful claims could result in significant legal fees and other expenses, diversion of management's time and disruption in our business. Uncertainties resulting from initiation and continuation of any patent proceeding or related litigation could harm our ability to compete and could have a significant adverse effect on our business, financial condition and results of operations.

[Table of Contents](#)

An adverse ruling arising out of any intellectual property dispute, including an adverse decision as to the priority of our inventions, could undercut or invalidate our intellectual property position. An adverse ruling could also subject us to significant liability for damages, including possible treble damages, prevent us from using technologies or developing products, or require us to negotiate licenses to disputed rights from third parties. Although patent and intellectual property disputes in the technology area are often settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and could include license fees and ongoing royalties. Furthermore, necessary licenses may not be available to us on satisfactory terms, if at all. Failure to obtain a license in such a case could have a significant adverse effect on our business, financial condition and results of operations.

To the extent we enter markets outside of the United States, our business will be subject to political, economic, legal and social risks in those markets, which could adversely affect our business.

There are significant regulatory and legal barriers in markets outside the United States that we must overcome to the extent we enter or attempt to enter markets in countries other than the United States. We will be subject to the burden of complying with a wide variety of national and local laws, including multiple and possibly overlapping and conflicting laws. We also may experience difficulties adapting to new cultures, business customs and legal systems. Any sales and operations outside the United States would be subject to political, economic and social uncertainties including, among others:

- changes and limits in import and export controls;
- increases in custom duties and tariffs;
- changes in currency exchange rates;
- economic and political instability;
- changes in government regulations and laws;
- absence in some jurisdictions of effective laws to protect our intellectual property rights; and
- currency transfer and other restrictions and regulations that may limit our ability to sell certain products or repatriate profits to the United States.

Any changes related to these and other factors could adversely affect our business to the extent we enter markets outside the United States.

Foreign governments often impose strict price controls on approved products, which may adversely affect our future profitability in those countries, and the re-importation of drugs to the United States from foreign countries that impose price controls may adversely affect our future profitability.

Frequently foreign governments impose strict price controls on newly approved therapeutic products. If we obtain regulatory approval to sell products in foreign countries, we may be unable to obtain a price that provides an adequate financial return on our investment. Furthermore, legislation in the United States may permit re-importation of drugs from foreign countries into the United States, including re-importation from foreign countries where the drugs are sold at lower prices than in the United States due to foreign government-mandated price controls. Such a practice, especially if it is conducted on a widespread basis, may significantly reduce our potential United States revenues from any drugs that we are able to develop.

If we elect not to sell our products in foreign countries that impose government mandated price controls because we decide it is uneconomical to do so, a foreign government or patent office may attempt to terminate our intellectual property rights in that country, enabling competitors to make and sell our products.

In some cases we may choose not to sell a product in a foreign country because it is uneconomical to do so under a system of government-imposed price controls, or because it could severely limit our profitability in the United States or other markets. In such cases, a foreign government or patent office may terminate any intellectual property rights we may obtain with respect to that product. Such a termination could enable competitors to produce and sell our product in that market. Furthermore, such products may be exported into the United States through legislation that authorizes the importation of drugs from outside the United States. In such an event, we may have to reduce our prices, or we may be unable to compete with low-cost providers of our drugs, and we could be financially harmed as a result.

We may encounter difficulties managing our growth, which could adversely affect our business.

At various times we have experienced periods of rapid growth in our employee numbers as a result of a dramatic increase in activity in technology programs, genomics programs, collaborative research programs, discovery programs, and scope of operations. At other times, we had to reduce staff in order to bring our expenses in line with our financial resources. Our success will also depend on the ability of our officers and key employees to continue to improve our operational capabilities and our management information and financial control systems, and to expand, train and manage our work force.

If we acquire products, technologies or other businesses, we will incur a variety of costs, may have integration difficulties and may experience numerous other risks that could adversely affect our business.

To remain competitive, we may decide to acquire additional businesses, products and technologies. We currently have no commitments or agreements with respect to, and are not actively seeking, any material acquisitions. We have limited experience in identifying acquisition targets, successfully acquiring them and integrating them into our current infrastructure. We may not be able to successfully integrate any businesses, products, technologies or personnel that we might acquire in the future without a significant expenditure of operating, financial and management resources, if at all. In addition, future acquisitions could require significant capital infusions and could involve many risks, including, but not limited to the following:

- we may have to issue convertible debt or equity securities to complete an acquisition, which would dilute our stockholders and could adversely affect the market price of our common stock;
- an acquisition may negatively impact our results of operations because it may require us to incur large one-time charges to earnings, amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or it may cause adverse tax consequences, substantial depreciation or deferred compensation charges;
- we may encounter difficulties in assimilating and integrating the business, technologies, products, personnel or operations of companies that we acquire;
- certain acquisitions may disrupt our relationship with existing collaborators who are competitive to the acquired business;
- acquisitions may require significant capital infusions and the acquired businesses, products or technologies may not generate sufficient revenue to offset acquisition costs;
- an acquisition may disrupt our ongoing business, divert resources, increase our expenses and distract our management;
- acquisitions may involve the entry into a geographic or business market in which we have little or no prior experience; and
- key personnel of an acquired company may decide not to work for us.

Any of the foregoing risks could have a significant adverse effect on our business, financial condition and results of operations.

Increased information technology security threats and more sophisticated and targeted computer crime could pose a risk to our systems, networks, and products.

Increased global information technology security threats and more sophisticated and targeted computer crime pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data and communications. While we attempt to mitigate these risks by employing a number of measures, including employee refreshers, monitoring of our networks and systems, and maintenance of backup and protective systems, our systems, networks and products remain potentially vulnerable to advanced persistent threats. Depending on their nature and scope, such threats could potentially lead to the compromising of confidential information and communications, improper use of our systems and networks, manipulation and destruction of data, defective products, production downtimes and operational disruptions, which in turn could adversely affect our reputation, competitiveness and results of operations.

We may not be able to utilize a significant portion of our net operating loss or research tax credit carryforwards or other tax attributes, which could harm our profitability.

At December 31, 2016, we had U.S. federal net operating loss and research and development tax credit carryforwards of approximately \$113,080,000 and \$5,842,000, respectively. Such operating losses and tax credits may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2020 and 2036. We also had foreign net operating loss carryforwards and foreign tax credit carryforwards of approximately \$14,863,000 and \$175,000, respectively. Such foreign net operating loss carryforwards do not expire and foreign tax credit carryforwards will expire between 2017 and 2021. We also had state and city net operating loss carryforwards aggregating approximately \$57,881,000. Such operating losses may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2017 and 2036.

[Table of Contents](#)

The utilization of net operating loss and tax credit carryforwards generated prior to October 2012 (the “Section 382 Limited Attributes”) is substantially limited under Section 382 of the Internal Revenue Code of 1986, as amended, as a result of our equity offering that occurred in October 2012. We generated U.S. federal net operating loss carryforwards of \$76,420,000, research and development tax credits of \$5,842,000, and state and local net operating loss carryforwards of \$56,919,000 since 2012. We will update our analysis under Section 382 prior to using these attributes.

Our ability to utilize of tax attributes that are not part of the Section 382 Limited Attributes may also be limited if we experience an “ownership change.” A Section 382 “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. The February 2017 offering or other issuances or sales of our common stock (including certain transactions involving our common stock that are outside of our control) could cause an “ownership change.” If an “ownership change” occurs, Section 382 of the Code would impose an annual limit on the amount of pre-ownership change net operating loss carryforwards and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. It is possible that such an ownership change could materially reduce our ability to use our net operating loss carryforwards or other tax attributes to offset taxable income, which could harm our profitability.

If we do not continue to meet the listing standards established by The NASDAQ Capital Market, the common stock may not remain listed for trading.

The NASDAQ Capital Market has established certain quantitative criteria and qualitative standards that companies must meet in order to remain listed for trading on these markets. We cannot guarantee that we will be able to maintain all necessary requirements for listing; therefore, we cannot guarantee that our common stock will remain listed for trading on The NASDAQ Capital Market or other similar markets.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our principal offices are located at 3201 Carnegie Avenue in Cleveland, Ohio. We currently lease approximately 45,000 square feet of space for our corporate offices and laboratories, with state-of-the-art laboratory space. The lease began in 2000 and currently expires in March 2018, and we have the option to renew annually through 2019. Our rent is \$267,000 per year and our rental rate has not changed since the lease inception in 2000. Also, we currently lease office and laboratory space for our Belgian subsidiary. The lease currently expires in July 2017, and we have an option to renew annually through July 2022. The annual rent in Belgium is approximately \$172,000 and is subject to adjustments based on an inflationary index. Our total rent expense for all properties was \$465,000 in 2016.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become subject to various legal proceedings that are incidental to the ordinary conduct of our business. Currently, there are no such proceedings.

ITEM 3A. EXECUTIVE OFFICERS OF THE REGISTRANT

The information under this Item is furnished pursuant to Instruction 3 to Item 401(b) of Regulation S-K.

There exists no arrangement or understanding between any executive officer and any other person pursuant to which such executive officer was elected. Each executive officer serves until his or her successor is elected and qualified.

The following sets forth the name, age, current position and principal occupation and employment during the past five years of our executive officers.

Gil Van Bokkelen, Ph.D.

Age: 56

Dr. Van Bokkelen has served as our Chief Executive Officer and Chairman since August 2000. Dr. Van Bokkelen co-founded Athersys in 1995 and has served as Chief Executive Officer and Director since the Company's founding. Prior to May 2006, he also served as the Company's President. Dr. Van Bokkelen is also the Chairman of the Board of Governors for the National Center for Regenerative Medicine. He served as the Chairman of the Alliance for Regenerative Medicine from 2010 through 2012, a Washington D.C. based consortium of companies, patient advocacy groups, disease foundations, and clinical and research institutions that are committed to the advancement of the field of regenerative medicine, and served *ex officio* from 2013 to 2014. He has served on a number of other boards, including the Biotechnology Innovation Organization's ECS board of directors (from 2001 to 2004, and from 2008 to present). He received his Ph.D. in Genetics from Stanford University School of Medicine, his B.A. in Economics from the University of California at Berkeley, and his B.A. in Molecular Biology from the University of California at Berkeley.

Dr. Van Bokkelen brings to the Board leadership, extensive business, operating, financial and scientific experience, and tremendous knowledge of our Company and the biotechnology industry. Dr. Van Bokkelen also brings his broad strategic vision for our Company to the Board of Directors and his service as the Chairman and Chief Executive Officer of Athersys creates a critical link between management and the Board, enabling the Board to perform its oversight function with the benefit of management's perspectives on the business. In addition, having the Chief Executive Officer, and Dr. Van Bokkelen, in particular, on our Board of Directors provides our Company with ethical, decisive and effective leadership.

John J. Harrington, Ph.D.

Age: 49

Dr. Harrington co-founded Athersys in 1995 and has served as our Chief Scientific Officer, Executive Vice President and Director since our founding. Dr. Harrington led the development of the RAGE[®] technology, as well as its application for gene discovery, drug discovery and commercial protein production applications. He is a listed inventor on over 20 issued or pending United States patents, has authored numerous scientific publications, and has received numerous awards for his work, including being named one of the top international young scientists by MIT Technology Review in 2002. Dr. Harrington has overseen the therapeutic product development programs at Athersys since their inception, and is also focused on the clinical development and manufacturing of MultiStem[®]. During his career, he has also held positions at Amgen and Scripps Clinic. He received his B.A. in Biochemistry and Cell Biology from the University of California at San Diego and his Ph.D. in Cancer Biology from Stanford University.

[Table of Contents](#)

Dr. Harrington's scientific experience and deep understanding of our Company, combined with his drive for innovation and excellence, position him well to serve on the Board of Directors.

William (BJ) Lehmann, Jr., J.D.

Age: 51

Mr. Lehmann joined Athersys in September 2001 and has served as our President and Chief Operating Officer since June 2006. Prior to that time, Mr. Lehmann was Athersys' Executive Vice President of Corporate Development and Finance from August 2002 until June 2006, when he became Athersys' President and Chief Operating Officer. From 1994 to 2001, Mr. Lehmann was with McKinsey & Company, Inc., an international management consulting firm, where he worked extensively with new technology and service-based businesses in the firm's Business Building practice. Prior to joining McKinsey, he worked at Wilson, Sonsini, Goodrich & Rosati, a Silicon Valley law firm, and worked with First Chicago Corporation, a financial institution. Mr. Lehmann received his J.D. from Stanford University, his M.B.A. from the University of Chicago, and his B.A. from the University of Notre Dame.

Laura K. Campbell, CPA

Age: 53

Ms. Campbell joined Athersys in January 1998 and has served as our Senior Vice President of Finance since March 2016. Ms. Campbell served as our Controller from January 1998, followed by Director of Finance and Senior Director of Finance, and then served as our Vice President of Finance from June 2006 until March 2016. Prior to joining Athersys, she was at Ernst & Young LLP, a public accounting firm, for eleven years in the firm's audit practice. During her tenure with Ernst & Young LLP, Ms. Campbell specialized in entrepreneurial services and the biotechnology industry sector and participated in several initial public offerings. Ms. Campbell received her B.S., with distinction, in Business Administration from The Ohio State University and is a certified public accountant.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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

Our common stock is traded on the NASDAQ Capital Market under the symbol "ATHX." Set forth below are the high and low sale prices for our common stock on the NASDAQ Capital Market for the periods indicated.

| | <u>High</u> | <u>Low</u> |
|--------------------------------------|-------------|------------|
| Year ended December 31, 2016: | | |
| Fourth Quarter | \$2.29 | \$1.41 |
| Third Quarter | \$2.35 | \$1.85 |
| Second Quarter | \$2.60 | \$1.80 |
| First Quarter | \$2.90 | \$0.98 |
| Year ended December 31, 2015: | | |
| Fourth Quarter | \$1.19 | \$0.94 |
| Third Quarter | \$1.57 | \$1.00 |
| Second Quarter | \$3.23 | \$0.90 |
| First Quarter | \$3.43 | \$1.54 |

Holders

As of February 28, 2017, there were approximately 525 holders of record of our common stock. Additionally, shares of common stock are held by financial institutions as nominees for beneficial owners that are deposited into participant accounts at the Depository Trust Company, which are considered to be held of record by Cede & Co. and are included in the holders of record as one stockholder.

Dividend Policy

We would have to rely upon dividends and other payments from our wholly owned subsidiary, ABT Holding Company, to generate the funds necessary to make dividend payments, if any, on our common stock. ABT Holding Company, however, is legally distinct from us and has no obligation to pay amounts to us. The ability of ABT Holding Company to make dividend and other payments to us is subject to, among other things, the availability of funds and applicable state laws. However, there are no restrictions such as government regulations or material contractual arrangements that restrict the ability of ABT Holding Company to make dividend and other payments to us. We did not pay cash dividends on our common stock during the past three years. We do not anticipate that we will pay any dividends on our common stock in the foreseeable future. Rather, we anticipate that we will retain earnings, if any, for use in the development of our business .

ITEM 6. SELECTED FINANCIAL DATA

(in thousands, except per share data)

| | Year Ended December 31, | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | 2016 | 2015 | 2014 | 2013 | 2012 |
| Consolidated Statement of Operations Data: | | | | | |
| Revenues: | | | | | |
| Contract revenue | \$ 16,238 | \$ 10,298 | \$ 286 | \$ 755 | \$ 7,380 |
| Grant revenue | 1,109 | 1,650 | 1,337 | 1,683 | 1,328 |
| Total revenues | 17,347 | 11,948 | 1,623 | 2,438 | 8,708 |
| Costs and expenses: | | | | | |
| Research and development | 24,838 | 21,316 | 23,366 | 20,484 | 19,636 |
| General and administrative | 7,835 | 7,536 | 6,909 | 6,065 | 4,753 |
| Depreciation | 382 | 267 | 360 | 346 | 320 |
| Total costs and expenses | 33,055 | 29,119 | 30,635 | 26,895 | 24,709 |
| Gain from insurance proceeds, net | 682 | — | — | — | — |
| Loss from operations | (15,026) | (17,171) | (29,012) | (24,457) | (16,001) |
| Other income (expense): | | | | | |
| (Expense) income from change in fair value of warrants | (557) | 772 | 6,591 | (6,324) | 2,404 |
| Other income (expense), net | 209 | (61) | 86 | 38 | (1,138) |
| Loss before income taxes | (15,374) | (16,460) | (22,335) | (30,743) | (14,735) |
| Income tax benefit | 37 | 38 | 253 | — | — |
| Net loss | <u>\$(15,337)</u> | <u>\$(16,422)</u> | <u>\$(22,082)</u> | <u>\$(30,743)</u> | <u>\$(14,735)</u> |
| Net loss per share, basic | <u>\$ (0.18)</u> | <u>\$ (0.20)</u> | <u>\$ (0.29)</u> | <u>\$ (0.53)</u> | <u>\$ (0.45)</u> |
| Weighted average shares outstanding, basic | 84,715 | 82,144 | 76,955 | 57,675 | 32,557 |
| Net loss per share, diluted | <u>\$ (0.18)</u> | <u>\$ (0.20)</u> | <u>\$ (0.31)</u> | <u>\$ (0.53)</u> | <u>\$ (0.45)</u> |
| Weighted average shares outstanding, diluted | 84,715 | 82,851 | 78,541 | 57,675 | 32,557 |
| | | | | | |
| | December 31, | | | | |
| | 2016 | 2015 | 2014 | 2013 | 2012 |
| Consolidated Balance Sheet Data: | | | | | |
| Cash and cash equivalents | \$ 14,753 | \$ 23,027 | \$ 26,127 | \$ 31,948 | \$ 25,533 |
| Working capital, excluding note payable | 9,405 | 19,251 | 22,556 | 28,487 | 21,831 |
| Total assets | 19,060 | 25,129 | 28,718 | 34,188 | 27,603 |
| Warrant liabilities and note payable | 1,004 | 839 | 3,131 | 9,999 | 2,878 |
| Total stockholders' equity | 11,181 | 19,724 | 20,895 | 19,821 | 20,247 |

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

You should read the following discussion and analysis in conjunction with “Item 8. Financial Statements and Supplementary Data” included below in this annual report on Form 10-K.

Overview

We are an international biotechnology company that is focused primarily in the field of regenerative medicine. Our MultiStem[®] cell therapy, a patented and proprietary allogeneic stem cell product, is our lead platform product and is currently in later-stage clinical development. Our current clinical development programs are focused on treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, certain pulmonary conditions and other conditions where the current standard of care is limited or inadequate for many patients.

Current Programs

By applying our proprietary MultiStem cell therapy product, we established therapeutic product development programs treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, and other conditions. Our programs in the clinical development stage include the following:

- **Ischemic Stroke**: We completed our Phase 2 study of MultiStem treatment of patients suffering a moderate to severe ischemic stroke and announced the one-year follow-up data and final results from the study in February 2016. We are actively engaged in advancing the next stage of clinical development of this program, both independently and with Healios. In September 2016, we announced that we received agreement from the FDA under a SPA for the design and planned analysis of a pivotal Phase 3 clinical trial of MultiStem cell therapy for the treatment of ischemic stroke. The SPA provides agreement from the FDA that the protocol design, clinical endpoints, planned conduct and statistical analyses encompassed in Athersys' planned Phase 3 study are acceptable to support a regulatory submission for approval of the MultiStem product for treating ischemic stroke patients. If the trial is successful, we believe the results from our Phase 3 MASTERS-2 clinical trial, together with other available clinical data, would provide the foundation of the regulatory package to be submitted for marketing approval.

Our MASTERS-2 clinical trial will be a randomized, double-blind, placebo-controlled clinical trial designed to enroll 300 patients in North America and Europe who have suffered moderate to moderate-severe ischemic stroke. The enrolled subjects will receive either a single intravenous dose of MultiStem cell therapy or placebo, administered within 18-36 hours of the occurrence of the stroke, in addition to the standard of care. The primary endpoint will evaluate disability using modified Rankin Scale, or mRS, scores at three months, comparing the distribution, or the “shift” between the MultiStem treatment and placebo groups. The mRS shift analyzes patient improvement across the full disability spectrum, enabling recognition of improvements in disability and differences in mortality and other serious outcomes, among strokes of different severities. The study will also assess Excellent Outcome (the achievement of mRS ≤ 1 , NIHSS ≤ 1 , and Barthel Index ≥ 95) at three months and one year as key secondary endpoints. Additionally, the study will consider other measures of functional recovery, biomarker data and clinical outcomes, including hospitalization, mortality and life-threatening adverse events, and post-stroke complications such as infection.

Also in September 2016, we announced the successful completion of the PMDA review of Healios' CTN, allowing Healios to commence its confirmatory clinical trial, TREASURE, evaluating the safety and efficacy of administration of MultiStem cell therapy for the treatment of ischemic stroke in Japan, which will be evaluated under the new regulatory framework for regenerative medicine therapies. In accordance with the regulatory system in Japan, a CTN is equivalent to an IND, under the regulatory system used in the United States. This clinical trial to be conducted in Japan is part of a partnership and license agreement between Healios and Athersys, focused on the development and commercialization of MultiStem in Japan for the treatment of ischemic stroke, and potentially other indications. The study design was accepted as proposed to PMDA in the CTN.

Healios' TREASURE study in Japan will be a randomized, double-blind, placebo-controlled clinical trial conducted at hospitals in Japan that have extensive experience at providing care for stroke victims. Based on the experience from our B01-02 study, subjects enrolled in the trial will receive either a single dose of MultiStem or placebo, administered within 18–36 hours of the occurrence of the stroke, in addition to standard of care. The study will evaluate patient recovery through approximately 90 days following initial treatment based on Excellent Outcome and other neurological, functional and clinical endpoints.

We intend to be prepared to launch our MASTERS-2 clinical trial in 2017 and will update our stockholders as we move forward with these plans. The Healios TREASURE clinical trial in Japan was presented at the International Stroke Conference in February 2017, and according to Healios, the study is expected to be complete in the second half of 2018.

• Acute Myocardial Infarction : We have an ongoing Phase 2 clinical study in the United States for the administration of MultiStem cell therapy to patients that have suffered an AMI. We previously evaluated the administration of MultiStem to patients that suffered an AMI in a Phase 1 clinical study. The results of this study demonstrated a favorable safety profile and encouraging signs of improvement in heart function among patients that exhibited severely compromised heart function prior to treatment. This data was published in a leading peer reviewed scientific journal, and one-year follow-up data suggested that the benefit observed was sustained over time. We were awarded in 2013 a grant for up to \$2.8 million in funding to support the advancement of this clinical program, and we are currently enrolling patients in our Phase 2 clinical study, evaluating the safety and efficacy of MultiStem treatment in subjects who have a non-ST elevated myocardial infarction. The study is double-blind, sham-controlled and is being conducted at leading cardiovascular centers in the United States. Since the rate of enrollment in this study has been below our expectations based on our historical data, we have taken steps to increase enrollment rates that have recently been implemented.

• Acute Respiratory Distress Syndrome : We have also initiated a clinical study for the treatment of ARDS in the United Kingdom and in the United States. In 2015, we were awarded a grant from Innovate UK for up to approximately £2.0 million as partial support of a Phase 1/2 clinical study evaluating the administration of MultiStem cell therapy to ARDS patients. ARDS is a serious immunological and inflammatory condition characterized by widespread inflammation in the lungs that severely compromises pulmonary function, requiring patients to be placed on a ventilator. ARDS can be triggered by pneumonia, sepsis, or other trauma and represents a major cause of morbidity and mortality in the critical care setting. The Phase 1/2 clinical trial is active, although initial patient accrual has been slower than expected, and we have taken steps to improve enrollment.

• Hematopoietic Stem Cell Transplant / GvHD : We completed a Phase 1 clinical study of the administration of MultiStem cell therapy to patients suffering from leukemia or certain other blood-borne cancers in which patients undergo radiation therapy and then receive a hematopoietic stem cell transplant. Such patients are at significant risk for serious complications, including GvHD an imbalance of immune system function caused by transplanted cells that trigger an attack against various tissues and organs in the patient. Data from the study demonstrated the safety of MultiStem cell therapy in this indication and suggested that the treatment may have a beneficial effect in reducing the incidence and severity of GvHD, as well as providing other benefits. We were granted orphan drug designation by the FDA and the EMA, for MultiStem treatment in the prevention of GvHD. In 2015, the MultiStem product was granted Fast Track designation by the FDA for prophylaxis therapy against GvHD following hematopoietic cell transplantation. Subsequently, our registration study design received a positive opinion from the EMA through the Protocol Assessment/Scientific Advice procedure. Furthermore, in December 2015, the proposed registration study received Special Protocol Assessment designation from the FDA, meaning that the trial is adequately designed to support a biologics license application, or BLA, submission for registration if it is successful. Currently, we are staging this program for future registration-directed development dependent on the achievement of certain business development and financial objectives and the development and success of alternative therapies for treating the underlying conditions leading to transplant.

While development of our clinical programs for human health indications remains our priority, based on our research to date and work performed at ReGenesys, we are evaluating our cell therapy for use in treating disease and conditions in the animal health segment. We and ReGenesys have demonstrated in preclinical animal health models that MultiStem cell therapy can promote tissue repair and healing that could provide meaningful benefits to animal patients, including those suffering from conditions with unmet medical need. In January 2017, we entered into an evaluation and option agreement with a global leader in the animal health business segment to evaluate our cell therapy technology for application in an undisclosed animal health area. We received a payment in exchange for an exclusive period to evaluate our cell therapy technology with an option to negotiate for a license for the development and commercialization of the technology for the animal health area.

We are engaged in preclinical development and evaluation of MultiStem therapy in other indications, focusing on the neurological, cardiovascular and inflammatory and immune disease areas, and we conduct such work both through our own internal research efforts and through a broad global network of collaborators. We are routinely in discussions with third parties about collaborating in the development of MultiStem therapy for various programs and may enter into one or more business partnerships to advance these programs over time.

[Table of Contents](#)

The MultiStem product platform continues to advance, we are engaged in process development initiatives intended to increase manufacturing scale, reduce production costs, and enhance process controls and product quality, among other things. These initiatives are being conducted both internally and outsourced to select contractors, and the related investments are meant to enable us to meet potential commercial demand in the event of eventual regulatory approval. Until such time as we are able to manufacture products ourselves in accordance with GMP, we will continue to rely on third party manufacturers to make our MultiStem product for clinical trials and commercial sales. These third parties may not deliver sufficient quantities of our MultiStem product, manufacture MultiStem product in accordance with specifications, or comply with applicable government regulations. From time to time, such third party manufacturers, or their material suppliers, may experience production delays, stoppages or interruptions in supply, which may affect the initiation, execution and timing of completion of clinical trials or commercial activities.

In January 2016, we entered into a license agreement with Healios to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan, and to provide Healios with access to our proprietary technologies for use in Healios' proprietary "organ bud" program, initially for transplantation to treat liver disease or dysfunction. Under the agreement, Healios also obtained a right to expand the scope of the collaboration to include the exclusive rights to develop and commercialize MultiStem for the treatment of two additional indications in Japan, which include ARDS and another indication in the orthopedic area, as well as all indications for the "organ bud" program. Healios is working toward the development and commercialization of the MultiStem product in Japan, and we are providing the manufactured product to Healios for its clinical studies.

We also have a collaboration with RTI for the development of products for certain orthopedic applications using our stem cell technologies in the bone graft substitutes market, and we have been earning royalty revenue from product sales since 2014 and may receive other payments upon the successful achievement of certain commercial milestones.

We have also developed other earlier stage cell-based and small molecule programs targeted at indications with significant unmet needs. We may elect to enter into partnerships to advance the development of these programs, as well as certain programs involving MultiStem therapy.

Financial

In February 2017, we completed a public offering generating net proceeds of approximately \$20.9 million through the issuance of 22,772,300 shares of common stock at an offering price of \$1.01 per share.

In connection with our January 2016 license agreement with Healios, we received an up-front cash payment of \$15 million from Healios, and the collaboration can be expanded at Healios' election. If Healios expands the collaboration, we will be entitled to receive an additional cash payment of \$10 million. Healios may exercise its option to expand the collaboration after receipt of the initial results from our ongoing ARDS clinical trial.

For the ischemic stroke indication, we may also receive additional success-based development and regulatory approval milestones and potential sales milestones from Healios aggregating up to \$225 million. We will also receive tiered royalties on product sales, starting in the low double digits and increasing incrementally into the high teens depending on net sales levels. Additionally, we will receive payments for product supplied to Healios under a manufacturing supply agreement.

If Healios exercises the option to expand to collaboration, we would be entitled to receive royalties from product sales and success-based development, regulatory approval and sales milestones, and payments for product supply for the additional indications, as well as a fractional royalty percentage on net sales of the organ bud products.

In October 2015, we and Chugai Pharmaceuticals Co., Ltd., or Chugai, agreed to terminate the License Agreement (the "Chugai Agreement"), dated February 28, 2015, between the parties, as a result of an inability to reach an agreement on the modification of the financial terms of the Chugai Agreement and on the development strategy, as proposed by Chugai, of our MultiStem cell therapy for the treatment of ischemic stroke in Japan. Pursuant to the terms of the Chugai Agreement, upon termination, we regained all rights for developing our stem cell technologies and products for ischemic stroke in Japan, retained the non-refundable up-front cash payment of \$10 million from Chugai, and Chugai no longer has any license rights or options with respect to our technologies and products. Neither we nor Chugai have any further obligations to each other.

We have in place an equity purchase agreement with Aspire Capital Fund LLC, or Aspire Capital, which provides us the ability to sell shares to Aspire Capital from time-to-time, as appropriate. Under our facility that was renewed in December 2015, we can elect to sell to Aspire Capital up to an additional \$30 million of shares of common stock under the agreement. During the quarter ended December 31, 2016, 1,050,000 shares were sold under the Aspire Capital equity purchase agreement at an average price of \$1.56, and during the year ended December 31, 2016, we sold 2,191,418 shares to Aspire Capital at an average price of \$1.84.

During the year ended December 31, 2016, we received proceeds of approximately \$163,000 from the exercise of warrants, resulting in the issuance of 161,366 shares of common stock in the aggregate.

In 2015, we and Catapult were awarded a grant from Innovate UK as partial support of a Phase 1/2 clinical study evaluating the administration of MultiStem cell therapy to ARDS patients. The grant is expected to provide up to approximately £2.0 million in aggregate support over the course of the study, which is currently enrolling patients.

Results of Operations

Since our inception, our revenues have consisted of license fees, contract revenues and milestone payments from our collaborators, and grant proceeds primarily from federal, state and foundation grants. We have derived no revenue from the commercial sale of therapeutic products to date, but we receive royalties on commercial sales by a licensee of products using our technologies. Research and development expenses consist primarily of external clinical and preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property prosecution processes, facility costs, and laboratory supply and reagent costs. We expense research and development costs as they are incurred. We expect to continue to make significant investments in research and development to enhance our technologies, advance clinical trials of our product candidates, expand our regulatory affairs and product development capabilities, conduct preclinical studies of our product and manufacture our product candidates. General and administrative expenses consist primarily of salaries and related personnel costs, professional fees and other corporate expenses. We expect to continue to incur substantial losses through at least the next several years.

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

Revenues. Revenues increased to \$17.3 million for the year ended December 31, 2016 from \$11.9 million in 2015, related primarily to the \$15.0 million payment received from the Healios collaboration in January 2016 that was recognized as revenue in the first quarter of 2016. The year ended December 31, 2015 includes the \$10.0 million payment received from Chugai that was recognized in the fourth quarter of 2015 upon the collaboration's termination in October 2015. We expect our future contract revenues to be comprised primarily of revenues associated with our Healios collaboration, royalty payments and potential commercial milestone payments from RTI, and proceeds from potential new collaborations. Grant revenue decreased \$0.5 million for the year ended December 31, 2016 compared to the year ended December 31, 2015, primarily due to completed grants and the timing of grant-funded projects. Our grant revenues fluctuate from period-to-period based on new grant awards, completed grants and the timing of grant-related activities.

Research and Development Expenses. Research and development expenses increased to \$24.8 million for the year ended December 31, 2016 from \$21.3 million for the year ended December 31, 2015. The increase of \$3.5 million related primarily to an increase in clinical and preclinical development costs of \$3.0 million, an increase in personnel costs of \$0.2 million, an increase in legal and professional fees of \$0.2 million and an increase in research supplies of \$0.1 million. Our clinical and preclinical development costs primarily reflect costs associated with our MultiStem clinical trials and include contract research organization costs, clinical manufacturing costs, manufacturing process development costs, and clinical and regulatory consulting costs. The increase in our preclinical and clinical development costs is primarily due to increased manufacturing costs, clinical study costs and regulatory costs. The increase in legal fees was a result of increased patent expenses associated with patent prosecution, national filings, and interparty proceedings and related filings. Based on our planned clinical development, manufacturing and process development activities, we expect our 2017 annual research and development expenses to be similar to 2016, and such costs will vary over time based on clinical manufacturing campaigns, the timing and stage of clinical trials underway, and manufacturing process development activities. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

General and Administrative Expenses. General and administrative expenses increased to \$7.8 million in 2016 from \$7.5 million in 2015. The \$0.3 million increase in 2016 compared to 2015 was due primarily to an increase of \$0.2 million in personnel costs and an \$0.1 million increase in other outside services. We expect our general and administrative expenses to continue at similar levels in 2017.

Depreciation. Depreciation expense increased to \$0.4 million in 2016 from \$0.3 million in 2015 due to equipment purchases and assets placed in service as a result of the flood repairs.

Gain from Insurance Proceeds, net. The net insurance recovery gain of \$0.7 million during 2016 included the loss associated with remediated flood damage (e.g., removal, clean-up), netted against the aggregate insurance proceeds received. The net amount resulted in a gain since most of the replaced assets were fully-depreciated leasehold improvements.

Income (Expense) from Change in Fair Value of Warrants. Expense of \$0.6 million and income of \$0.8 million was recognized during the years ended December 31, 2016 and 2015, respectively, for the market value change in our warrant liabilities. The fluctuation is related to the impact of changes in warrant value, primarily affected by our stock price and the remaining lives of the issued warrants. Our warrants are expiring in the first quarter of 2017, and therefore, we will not be recognizing a fair value change beginning the second quarter of 2017.

[Table of Contents](#)

Other Income (Expense), net. Other income (expense), net, for the years ended December 31, 2016 and 2015 remained relatively consistent and was comprised of interest income and expense, and foreign currency gains and losses.

Income Tax Benefit. The income tax benefit in 2016 and 2015 represents refundable foreign tax credits.

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

Revenues. Revenues increased to \$11.9 million for the year ended December 31, 2015 from \$1.6 million in 2014, reflecting the \$10.0 million payment received from the Chugai collaboration that was terminated in October 2015. Grant revenue increased \$0.3 million for the year ended December 31, 2015 compared to the year ended December 31, 2014, primarily due to completed grants and the timing of grant-funded projects. Our grant revenues fluctuate from period-to-period based on new grant awards, completed grants and the timing of grant-related activities.

Research and Development Expenses. Research and development expenses decreased to \$21.3 million for the year ended December 31, 2015 from \$23.4 million for the year ended December 31, 2014. The decrease of \$2.1 million related primarily to a decrease in clinical and preclinical development costs of \$1.5 million, a decrease in sponsored research costs of \$0.5 million, a decrease in legal and professional fees of \$0.2 million, and a decrease in travel costs of \$0.2 million, with such decreases partially offset by an increase of \$0.2 million in license fees and a \$0.1 million increase in personnel costs for the year ended December 31, 2015 from 2014. Our clinical and preclinical development costs primarily reflect costs associated with our MultiStem clinical trials and include contract research organization costs, clinical manufacturing costs, manufacturing process development costs, and clinical and regulatory consulting costs. The decrease in our preclinical and clinical development costs is primarily due to decreased manufacturing costs, clinical study costs and regulatory costs. Sponsored research costs decreased primarily due to the timing of costs incurred by certain academic research institutions under our grant-funded programs. The decrease in legal fees was a result of decreased patent expenses associated with patent prosecution, national filings, and interparty proceedings and related filings. Other than external expenses for our clinical and preclinical programs, we do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

General and Administrative Expenses. General and administrative expenses increased to \$7.5 million in 2015 from \$6.9 million in 2014. The \$0.6 million increase in 2015 compared to 2014 was due primarily to an increase of \$0.2 million in stock-based compensation, an increase in professional fees of \$0.2 million and an increase of \$0.2 million in consulting costs. Stock-based compensation increased in 2015 compared to 2014 from the ratable expense of vesting awards issued in connection with our annual equity incentive program that began to include officers in 2013. The increase in professional and consulting fees costs related to our business development activities.

Depreciation. Depreciation expense decreased to \$0.3 million in 2015 from \$0.4 million in 2014 due to fewer equipment purchases.

Income (Expense) from Change in Fair Value of Warrants . Income of \$0.8 million and \$6.6 million was recognized during the years ended December 31, 2015 and 2014, respectively, for the market value change in our warrant liabilities. The fluctuation is related to the impact of new warrant issuances and changes in warrant value, primarily affected by our stock price and the remaining lives of the issued warrants.

Other Income (Expense), net. Other income (expense), net, for the years ended December 31, 2015 and 2014 remained relatively consistent and was comprised of interest income and expense, and foreign currency gains and losses.

Income Tax Benefit. The income tax benefit in 2015 and 2014 represents refundable foreign tax credits.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and any available-for-sale securities. At December 31, 2016, we had \$14.8 million in cash and cash equivalents. We have primarily financed our operations through business collaborations, grant funding and equity financings. We conduct all of our operations through our subsidiary, ABT Holding Company. Consequently, our ability to fund our operations depends on ABT Holding Company's financial condition and its ability to make dividend payments or other cash distributions to us. There are no restrictions such as government regulations or material contractual arrangements that restrict the ability of ABT Holding Company to make dividend and other payments to us.

We incurred losses since inception of operations in 1995 and had an accumulated deficit of \$318 million at December 31, 2016. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, acquisition and licensing costs, and general and administrative costs associated with our operations. We used the financing proceeds from equity and debt offerings and other sources of capital to develop our technologies, to discover and develop therapeutic product candidates, develop business collaborations and to acquire certain technologies and assets.

[Table of Contents](#)

In February 2017, we completed a public offering generating net proceeds of approximately \$20.9 million through the issuance of 22,772,300 shares of common stock at an offering price of \$1.01 per share.

In January 2014, we completed a registered direct offering generating net proceeds of approximately \$18.8 million through the issuance of 5,000,000 shares of common stock and warrants to purchase 1,500,000 shares of common stock with an exercise price of \$4.50 per share that expire on July 15, 2016. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.30 shares of common stock at an offering price of \$4.10 per fixed combination.

We have had an equity purchase arrangement in place with Aspire Capital since 2011, through two to three year equity facility agreements, each with similar terms. The current agreement with Aspire Capital was entered into in December 2015 and includes Aspire's commitment to purchase up to an aggregate of \$30.0 million of shares of our common stock over a new three-year period. The terms of the 2015 equity facility are similar to the previous arrangements, and we issued 250,000 shares of our common stock to Aspire Capital as a commitment fee in December 2015 and filed a registration statement for the resale of 16,600,000 shares of common stock in connection with the new equity facility. During the years ended December 31, 2016 and 2015, we sold 2,191,418 and 4,023,719 shares, respectively, to Aspire Capital at average prices of \$1.84 and \$2.58 per share, respectively. As of December 31, 2016, we received proceeds of approximately \$28.8 million in aggregate under the Aspire equity purchase agreements since its inception in 2011.

Investors in certain of our equity offerings have received warrants to purchase shares of our common stock, of which warrants to purchase an aggregate of 1.9 million shares remain outstanding at December 31, 2016 with an exercise price of \$1.01 per share and expire March 14, 2017. During the year ended December 31, 2016, we received proceeds of approximately \$163,000 from the exercise of warrants, resulting in the issuance of 161,366 shares of common stock in the aggregate. During the year ended December 31, 2015, we received proceeds of approximately \$1.0 million from the exercise of warrants, resulting in the issuance of 966,184 shares of common stock in the aggregate. Subsequent to December 31, 2016, we received proceeds of approximately \$0.4 million from the exercise of the warrants.

In connection with our January 2016 license agreement with Healios, we received an up-front cash payment of \$15 million from Healios, and the collaboration can be expanded at Healios' election. If Healios expands the collaboration, we will be entitled to receive an additional cash payment of \$10 million. Healios may exercise its option to expand the collaboration after the receipt of the initial results from Athersys' ongoing ARDS clinical trial. For the ischemic stroke indication, we may also receive additional success-based development and regulatory approval milestones potential sales milestones from Healios aggregating up to \$225 million. We will also receive tiered royalties on product sales, starting in the low double digits and increasing incrementally into the high teens depending on net sales levels. Additionally, we will receive payments for product supplied to Healios under a manufacturing supply agreement; provided, that, if we determine that we are not able to supply product at a defined price or a price otherwise agreeable to Healios after using commercially reasonable efforts, we may notify Healios and grant Healios it a license to make the product solely for use in the licensed field in Japan. In January 2017, we signed a clinical trial supply agreement for the manufacturing of investigational product for Healios for its Japan clinical study.

If Healios exercises the option to expand to collaboration, we would be entitled to receive royalties from product sales and success-based development, regulatory approval and sales milestones, and payments for product supply for the additional indications, as well as a fractional royalty percentage on net sales of the organ bud products.

In connection with our license agreement with Chugai that was terminated in October 2015, we received an up-front cash payment of \$10 million in 2015, but terminated the license agreement when the parties were unable to reach an agreement on the potential modification of the financial terms of the agreement and on the development strategy in Japan. We retained the \$10 million up-front cash payment from Chugai and regained all rights for developing our stem cell technologies and products for ischemic stroke in Japan, and Chugai no longer has any license rights or options with respect to our technologies and products. Neither we nor Chugai have any further obligations to each other.

Under the terms of our RTI agreement, we are eligible to receive cash payments aggregating up to \$35.5 million upon the successful achievement of certain commercial milestones, though there can be no assurance that such milestones will be achieved, and no significant milestone payments have been received as of December 31, 2016. In addition, we are entitled to receive tiered royalties on worldwide commercial sales of implants using our technologies based on a royalty rate starting in the mid-single digits and increasing into the mid-teens, and we began receiving royalty payments in 2014.

[Table of Contents](#)

We remain entitled to receive license fees for targets that were delivered to Bristol-Myers Squibb under our completed 2001 collaboration, as well as milestone payments and royalties on compounds developed by Bristol-Myers Squibb using our technology, though there can be no assurance that we will achieve any such milestones or royalties. Bristol-Myers Squibb still has a few active programs using our cell lines, and during 2016, we received a \$0.6 million milestone payment related to this collaboration.

We are obligated to pay the University of Minnesota a sublicense fee or a royalty based on worldwide commercial sales of licensed products if covered by a valid licensed patent. The low single-digit royalty rate may be reduced if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product. As of December 31, 2016, we have paid no royalties to the University of Minnesota and have paid sublicense fees from time-to-time in connection with our collaborations.

In 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center and the Cleveland Clinic Foundation in which we were entitled to proceeds of up to \$0.5 million in the form of a forgivable loan to fund certain preclinical work. In February 2016, the loan and accrued interest, which amounted to approximately \$0.2 million, was forgiven according to its terms based on our achievement of certain milestones.

In 2015, we and Catapult were awarded a grant from Innovate UK as partial support of a Phase 1/2 clinical study evaluating the administration of MultiStem cell therapy to ARDS patients. The grant is expected to provide up to approximately £2.0 million in support (of which £0.75 million is our portion) over the course of the study, which is currently enrolling patients.

We will require substantial additional funding in order to continue our research and product development programs, including preclinical evaluation and clinical trials of our product candidates and manufacturing process development. At December 31, 2016, we had available cash and cash equivalents of \$14.8 million, and we intend to meet our short-term liquidity needs with available cash. Over the longer term, we will make use of available cash, but will have to continue to generate additional funding to meet our needs, through business development, achievement of milestones under our collaborations, and grant-funding opportunities. Additionally, we may raise capital from time to time through our equity purchase agreement with Aspire Capital, subject to its volume and price limitations. We also manage our cash by deferring certain discretionary costs and staging certain development costs to extend our operational runway, as needed. Over time, we may consider the sale of additional equity securities, or possibly borrowing from financing institutions.

Our capital requirements over time depend on a number of factors, including progress in our clinical development programs, our clinical and preclinical pipeline of additional opportunities and their stage of development, additional external costs such as payments to contract research organizations and contract manufacturing organizations, additional personnel costs and the costs in filing and prosecuting patent applications and enforcing patent claims. The availability of funds impacts our ability to advance multiple clinical programs concurrently, and any shortfall in funding could result in our having to delay or curtail research and development efforts. Further, these requirements may change at any time due to technological advances, business development activity or competition from other companies. We cannot assure you that adequate funding will be available to us or, if available, that it will be available on acceptable terms.

We expect to continue to incur substantial losses through at least the next several years and may incur losses in subsequent periods. The amount and timing of our future losses are highly uncertain. Our ability to achieve and thereafter sustain profitability will be dependent upon, among other things, successfully developing, commercializing and obtaining regulatory approval or clearances for our technologies and products resulting from these technologies.

Cash Flow Analysis

Net cash used in operating activities was \$10.9 million, \$13.8 million and \$25.8 million in 2016, 2015 and 2014, respectively, and represented the use of cash to fund operations, clinical trials, and preclinical and process development activities; net of receipts from collaborative arrangements (e.g., Healios in 2016 and Chugai in 2015). Net cash used in operating activities may fluctuate significantly on a quarter-to-quarter basis, as it has over the past several years, primarily due to the receipt of collaboration fees and payment of specific clinical trial costs, such as clinical manufacturing campaigns, contract research organization costs, and manufacturing process development projects.

Net cash used in investing activities was \$1.1 million, \$0.1 million and \$0.3 million in 2016, 2015 and 2014, respectively, related to the purchase of equipment for our manufacturing process development activities in 2016, which was partially offset by proceeds from insurance related to a flood. We expect that our capital equipment expenditures will decrease in 2017 compared to 2016.

[Table of Contents](#)

Financing activities provided net cash of \$3.7 million in 2016 and \$10.8 million in 2015 related to the exercise of common stock warrants and equity sales to Aspire Capital, net of treasury stock payments. Financing activities provided net cash of \$20.3 million in 2014 related to the January 2014 registered direct offering, the exercise of common stock warrants and equity sales to Aspire Capital, net of treasury stock payments.

Our contractual payment obligations as of December 31, 2016 are as follows:

Payment due by Period

| Contractual Obligations | Total | Less than 1 Year | 1 – 3 Years | 3 – 5 Years | More than 5 Years |
|--|---------------------------|----------------------------|-------------------------|--------------------|--------------------------|
| Operating leases for facilities and equipment leases | \$ 465,000 | \$ 371,000 | \$ 94,000 | \$ — | \$ — |
| Reserved manufacturing space | 1,000,000 | 1,000,000 | — | — | — |
| | <u>\$1,465,000</u> | <u>\$ 1,371,000</u> | <u>\$ 94,000</u> | <u>\$ —</u> | <u>\$ —</u> |

We lease office and laboratory space under operating leases. Our lease for our corporate offices and laboratories began in 2000 and currently expires in March 2018, and we have the option to renew annually through 2019. Our rent is \$267,000 per year and our rental rate has not changed since the lease inception in 2000. Also, we lease office and laboratory space for our Belgian subsidiary that currently expires in July 2017 and includes options to renew annually through July 2022, and the annual rent of approximately \$172,000 is subject to adjustments based on an inflationary index. Our total rent expense for all properties was \$465,000 in 2016.

We have reserved space at a contract manufacturer to manufacture our cell therapy product for clinical development through May 2017.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Critical Accounting Policies and Management Estimates

The SEC defines critical accounting policies as those that are, in management's view, important to the portrayal of our financial condition and results of operation and demanding of management's judgment. Our discussion and analysis of financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates on experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates.

A discussion of the material implications of uncertainties associated with the methods, assumptions and estimates underlying our critical accounting policies is as follows:

Revenue Recognition

Our license and collaboration agreements may contain multiple elements, including license and technology access fees, research and development funding, manufacturing revenue, cost-sharing, milestones and royalties. The deliverables under such an arrangement are evaluated under Accounting Standards Codification, or ASC, 605-25, *Multiple-Element Arrangements*. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has "stand-alone value" to the customer. The arrangement's consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables.

For agreements entered into prior to January 1, 2011 and not materially modified thereafter (such as RTI and Bristol-Myers Squibb contract revenue), we applied our prior accounting policy and assessed whether arrangements had standalone value and objective and reliable evidence of fair value, and if so, were accounted for as a single unit. The performance period for such agreements has concluded. The remaining potential milestones from our Bristol-Myers Squibb arrangement were determined to be non-substantive and are recognized in the period that the milestone is achieved, since we have no remaining obligations under the agreement. The remaining potential commercial milestones from our RTI collaboration are recognized when earned. Both such milestones are included in contract revenues when earned.

We recognize revenue, in full, in the period that the milestone is achieved from at-risk, performance milestones that are related to our past performance and determined to be substantive at the inception of the arrangement.

We entered into collaboration agreements with Healios, Chugai and RTI that contain multiple elements and deliverables. For a description of the collaboration agreements and the determination of contract revenues, see Note E to our audited consolidated financial statements.

Grant revenue consists of funding under cost reimbursement programs primarily from federal and non-profit foundation sources for qualified research and development activities performed by us, and as such, are not based on estimates that are susceptible to change. Such amounts are invoiced and recorded as revenue as tasks are completed.

We recognize revenue from royalties relating to the sale by a licensee of the licensed product. Royalty revenue is recognized on an accrual basis in accordance with the substance of the relevant agreement and based on the receipt from the licensee of the relevant information to enable calculation of the royalty due.

Clinical Trial Costs

Clinical trial costs are accrued based on work performed by outside contractors that manage and perform the trials, and that manufacture clinical product. We obtain initial estimates of total costs based on enrollment of subjects, project management estimates, manufacturing estimates and other activities. Actual costs are typically charged to us and recognized as the tasks are completed by the contractor, and if we are invoiced based on progress payments as opposed to actual costs, we develop estimates of work completed to date. Accrued clinical trial costs may be subject to revisions as clinical trials progress, and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

Stock-Based Compensation

We recognize stock-based compensation expense on the straight-line method and use a Black-Scholes option-pricing model to estimate the grant-date fair value of share-based awards. The expected term of options granted represent the period of time that option grants are expected to be outstanding. We use the “simplified” method to calculate the expected life of option grants given our limited history and determine volatility by using our historical stock volatility. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates and if our expectations on forfeitures changes. If actual forfeitures vary from the estimate, we will recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

All of the aforementioned estimates and assumptions are evaluated on a quarterly basis and may change as facts and circumstances warrant. Changes in these assumptions can materially affect the estimate of the fair value of our share-based payments and the related amount recognized in our financial statements.

Collaborative Arrangements

Collaborative arrangements that involve cost or future profit sharing are reviewed to determine the nature of the arrangement and the nature of the collaborative parties’ businesses. The arrangements are also reviewed to determine if one party has sole or primary responsibility for an activity, or whether the parties have shared responsibility for the activity. If responsibility for an activity is shared and there is no principal party, then the related costs of that activity are recognized by us on a net basis in the statement of operations (e.g., total cost less reimbursement from collaborator). If we are deemed to be the principal party for an activity, then the costs and revenues associated with that activity are recognized on a gross basis in the statement of operations. The accounting may be susceptible to change if the nature of a collaborator’s business changes. Currently, we have no collaborations that are accounted for on a net basis.

Fair Value of Warrant Liabilities

The estimated fair value of warrants accounted for as liabilities, representing a level 3 fair value measure, is determined on the issuance date and subsequently marked to market at each financial reporting date. The fair value of the warrants is estimated using the expected volatility based on our historical volatility for warrants issued after January 1, 2013, or for warrants issued prior to 2013, using the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization, each of which using a Black-Scholes pricing model. The fair value of certain warrants is determined using probability weighted-average assumptions that give consideration to contractual terms in the warrants, such as an exercise price repricing feature, as defined.

Pending Adoption of New Accounting Pronouncements

Refer to Note B to the consolidated financial statements for a discussion of recently issued accounting standards.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. These forward-looking statements relate to, among other things, the expected timetable for development of our product candidates, our growth strategy, and our future financial performance, including our operations, economic performance, financial condition, prospects, and other future events. We have attempted to identify forward-looking statements by using such words as “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “should,” “suggest,” “will,” or other similar expressions. These forward-looking statements are only predictions and are largely based on our current expectations. These forward-looking statements appear in a number of places in this annual report.

In addition, a number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements. Some of the more significant known risks that we face are the risks and uncertainties inherent in the process of discovering, developing, and commercializing products that are safe and effective for use as human therapeutics, including the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues. The following risks and uncertainties may cause our actual results, levels of activity, performance, or achievements to differ materially from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements:

- our ability to raise capital to fund our operations;
- the timing and nature of results from our MultiStem clinical trials;
- the possibility of delays in, adverse results of, and excessive costs of the development process;
- our ability to successfully initiate and complete clinical trials of our product candidates;
- the possibility of delays, work stoppages or interruptions in manufacturing by third parties or us, such as due to material supply constraints or regulatory issues;
- uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the treatment of stroke, AMI and ARDS, and the prevention of GvHD and other disease indications;
- changes in external market factors;
- changes in our industry’s overall performance;
- changes in our business strategy;
- our ability to protect and defend our intellectual property and related business operations, including the successful prosecution of our patent applications and enforcement of our patent rights, and operate our business in an environment of rapid technology and intellectual property development;
- our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies;
- our ability to meet milestones and earn royalties under our collaboration agreements;
- our collaborators’ ability to continue to fulfill their obligations under the terms of our collaboration agreements;
- the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in the United States, Europe and Japan;
- our possible inability to execute our strategy due to changes in our industry or the economy generally;
- changes in productivity and reliability of suppliers;
- the success of our competitors and the emergence of new competitors; and
- the risks mentioned elsewhere in this annual report on Form 10-K under Item 1A, “Risk Factors.”

Although we currently believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee our future results, levels of activity or performance. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. You are advised, however, to consult any further disclosures we make on related subjects in our reports on Forms 10-Q, 8-K and 10-K furnished to the SEC. You should understand that it is not possible to predict or identify all risk factors. Consequently, you should not consider any such list to be a complete set of all potential risks or uncertainties.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our exposure to interest rate risk is related to our investment portfolio and our borrowings. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. Due in part to these factors, our future investment income may fall short of expectations. Further, we may suffer losses in investment principal if we are forced to sell securities that have declined in market value due to changes in interest rates. When appropriate based on interest rates, we invest our excess cash primarily in debt instruments of the United States government and its agencies and corporate debt securities, and as of December 31, 2016, we had no investments.

We have entered into loan arrangements with financial institutions when needed and when available to us. At December 31, 2016, we had no borrowings outstanding.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Athersys, Inc.

Consolidated Financial Statements

Years Ended December 31, 2016, 2015 and 2014

Contents

| | |
|---|----|
| Reports of Independent Registered Public Accounting Firm | 50 |
| Consolidated Balance Sheets as of December 31, 2016 and 2015 | 52 |
| Consolidated Statements of Operations and Comprehensive Loss for each of the years ended December 31, 2016, 2015 and 2014 | 53 |
| Consolidated Statements of Stockholders' Equity for each of the years ended December 31, 2016, 2015 and 2014 | 54 |
| Consolidated Statements of Cash Flows for each of the years ended December 31, 2016, 2015 and 2014 | 55 |
| Notes to Consolidated Financial Statements | 56 |

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Athersys, Inc.

We have audited the accompanying consolidated balance sheets of Athersys, Inc. and subsidiaries as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. Our audits also included the financial statement schedule listed in the Index at Item 15(a) (2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Athersys, Inc. and subsidiaries at December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Athersys, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 10, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Cleveland, Ohio
March 10, 2017

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Athersys, Inc.

We have audited Athersys, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control —Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Athersys Inc. and subsidiaries' 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 Management's Report on Internal Control over Financial Reporting in Item 9A. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Athersys, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016 of Athersys, Inc. and subsidiaries and our report dated March 10, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Cleveland, Ohio
March 10, 2017

Athersys, Inc.

Consolidated Balance Sheets

(In Thousands, Except Share and Per Share Amounts)

| | December 31, | |
|--|------------------|------------------|
| | 2016 | 2015 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 14,753 | \$ 23,027 |
| Accounts receivable | 598 | 361 |
| Prepaid expenses and other | 929 | 429 |
| Total current assets | 16,280 | 23,817 |
| Equipment, net | 2,605 | 1,135 |
| Deferred tax assets | 175 | 177 |
| Total assets | <u>\$ 19,060</u> | <u>\$ 25,129</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 4,761 | \$ 2,702 |
| Accrued compensation and related benefits | 1,190 | 1,024 |
| Accrued clinical trial costs | 389 | 82 |
| Accrued expenses | 535 | 513 |
| Note payable | — | 190 |
| Deferred revenue | — | 245 |
| Total current liabilities | 6,875 | 4,756 |
| Warrant liabilities | 1,004 | 649 |
| Stockholders' equity: | | |
| Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at December 31, 2016 and December 31, 2015 | — | — |
| Common stock, \$0.001 par value; 150,000,000 shares authorized, 86,629,302 and 83,720,154 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively | 87 | 84 |
| Additional paid-in capital | 329,373 | 322,582 |
| Accumulated deficit | (318,279) | (302,942) |
| Total stockholders' equity | 11,181 | 19,724 |
| Total liabilities and stockholders' equity | <u>\$ 19,060</u> | <u>\$ 25,129</u> |

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In Thousands, Except Share and Per Share Amounts)

| | Year Ended December 31, | | |
|--|-------------------------|--------------------|--------------------|
| | 2016 | 2015 | 2014 |
| Revenues | | | |
| Contract revenue | \$ 16,238 | \$ 10,298 | \$ 286 |
| Grant revenue | 1,109 | 1,650 | 1,337 |
| Total revenues | 17,347 | 11,948 | 1,623 |
| Costs and expenses | | | |
| Research and development (including stock compensation expense of \$1,192, \$1,277 and \$1,158 in 2016, 2015 and 2014, respectively) | 24,838 | 21,316 | 23,366 |
| General and administrative (including stock compensation expense of \$1,676, \$1,652 and \$1,447 in 2016, 2015 and 2014, respectively) | 7,835 | 7,536 | 6,909 |
| Depreciation | 382 | 267 | 360 |
| Total costs and expenses | 33,055 | 29,119 | 30,635 |
| Gain from insurance proceeds, net | 682 | — | — |
| Loss from operations | (15,026) | (17,171) | (29,012) |
| (Expense) income from change in fair value of warrants, net | (557) | 772 | 6,591 |
| Other income (expense), net | 209 | (61) | 86 |
| Loss before income taxes | (15,374) | (16,460) | (22,335) |
| Income tax benefit | 37 | 38 | 253 |
| Net loss and comprehensive loss | \$ (15,337) | \$ (16,422) | \$ (22,082) |
| Net loss per common share, basic | \$ (0.18) | \$ (0.20) | \$ (0.29) |
| Weighted average shares outstanding, basic | 84,715,471 | 82,143,610 | 76,954,503 |
| Net loss per common share, diluted | \$ (0.18) | \$ (0.20) | \$ (0.31) |
| Weighted average shares outstanding, diluted | 84,715,471 | 82,851,091 | 78,541,447 |

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Stockholders' Equity

(In Thousands, Except Share Amounts)

| | Preferred Stock | | Common Stock | | Additional | Treasury | Accumulated | Total |
|--|---------------------|-----------------|---------------------|--------------|--------------------|----------|--------------|-------------------------|
| | Number of Shares | Stated Value | Number of Shares | Par Value | Paid-in Capital | Stock | Deficit | Stockholders' Equity |
| Balance at January 1, 2014 | — | \$ — | 70,683,480 | 71 | \$ 284,323 | \$ (135) | \$ (264,438) | \$ 19,821 |
| Stock-based compensation | — | — | — | — | 2,605 | — | — | 2,605 |
| Issuance of common stock from warrant exercises | — | — | 928,924 | 1 | 868 | 69 | — | 938 |
| Issuance of common stock and warrants, net of issuance costs | — | — | 5,250,000 | 5 | 19,698 | 358 | — | 20,061 |
| Issuance of common stock under equity compensation plans | — | — | 844,412 | 1 | (157) | (292) | — | (448) |
| Net and comprehensive loss | — | — | — | — | — | — | (22,082) | (22,082) |
| Balance at December 31, 2014 | — | — | 77,706,816 | 78 | 307,337 | — | \$ (286,520) | \$ 20,895 |
| Stock-based compensation | — | — | — | — | 2,929 | — | — | 2,929 |
| Issuance of common stock from warrant exercises | — | — | 966,184 | 1 | 975 | — | — | 976 |
| Issuance of common stock, net of issuance costs | — | — | 4,273,719 | 4 | 11,831 | — | — | 11,835 |
| Issuance of common stock under equity compensation plans | — | — | 773,435 | 1 | (490) | — | — | (489) |
| Net and comprehensive loss | — | — | — | — | — | — | (16,422) | (16,422) |
| Balance at December 31, 2015 | — | — | 83,720,154 | 84 | 322,582 | — | \$ (302,942) | \$ 19,724 |
| Stock-based compensation | — | — | — | — | 2,868 | — | — | 2,868 |
| Issuance of common stock from warrant exercises | — | — | 161,366 | — | 163 | — | — | 163 |
| Issuance of common stock, net of issuance costs | — | — | 2,191,418 | 2 | 4,228 | — | — | 4,230 |
| Issuance of common stock under equity compensation plans | — | — | 556,364 | 1 | (468) | — | — | (467) |
| Net and comprehensive loss | — | — | — | — | — | — | (15,337) | (15,337) |
| Balance at December 31, 2016 | — | \$ — | 86,629,302 | \$ 87 | \$ 329,373 | \$ — | \$ (318,279) | \$ 11,181 |

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Cash Flows

(In Thousands)

| | Year Ended December 31, | | |
|---|-------------------------|------------------|------------------|
| | 2016 | 2015 | 2014 |
| Operating activities | | | |
| Net loss | \$ (15,337) | \$ (16,422) | \$ (22,082) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 382 | 267 | 360 |
| Gain from forgiveness of note payable | (190) | — | — |
| Stock-based compensation | 2,868 | 2,929 | 2,605 |
| Deferred tax benefit | 2 | 23 | (200) |
| Gain from insurance proceeds, net | (682) | — | — |
| Change in fair value of warrant liabilities | 557 | (772) | (6,591) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (237) | 333 | (174) |
| Prepaid expenses and other | (462) | 4 | (33) |
| Accounts payable and accrued expenses | 2,413 | (296) | 335 |
| Deferred revenue | (245) | 170 | (11) |
| Net cash used in operating activities | (10,931) | (13,764) | (25,791) |
| Investing activities | | | |
| Purchase of available-for-sale securities | (16,343) | — | — |
| Sales of available-for-sale securities | 16,305 | — | — |
| Proceeds from insurance | 682 | — | — |
| Purchases of equipment | (1,711) | (132) | (297) |
| Net cash used in investing activities | (1,067) | (132) | (297) |
| Financing activities | | | |
| Proceeds from issuance of common stock and warrants, net | 4,028 | 10,310 | 19,621 |
| Proceeds from exercise of warrants | 163 | 976 | 938 |
| Purchase of treasury stock | (467) | (490) | (292) |
| Net cash provided by financing activities | 3,724 | 10,796 | 20,267 |
| Decrease in cash and cash equivalents | (8,274) | (3,100) | (5,821) |
| Cash and cash equivalents at beginning of year | 23,027 | 26,127 | 31,948 |
| Cash and cash equivalents at end of year | \$ 14,753 | \$ 23,027 | \$ 26,127 |

See accompanying notes.

Athersys, Inc.

Notes to Consolidated Financial Statements

A. Background

We are an international biotechnology company that is focused primarily in the field of regenerative medicine and operate in one business segment. Our operations consist primarily of research and later-stage product development activities.

We incurred losses since our inception in 1995 and had an accumulated deficit of \$318 million at December 31, 2016. We will require substantial additional capital to continue our research and development programs, including progressing our clinical product candidates to commercialization and preparing for commercial-scale manufacturing. At December 31, 2016, we had available cash and cash equivalents of \$14.8 million, and we believe that these funds, together with the \$20.9 million of net proceeds from our February 2017 public offering of common stock, and our existing operating plans, are sufficient to meet our obligations as they come due at least for a period of twelve months from the date of the issuance of these consolidated financial statements. In the longer-term, we will make use of available cash, but will have to continue to generate additional capital to meet our needs through new and existing collaborations and related milestones, grant-funding opportunities, deferring certain discretionary costs and staging certain development costs, as needed, and the sale of equity securities from time to time, including through our equity purchase agreement with Aspire Capital Fund LLC ("Aspire Capital").

B. Accounting Policies

Principles of Consolidation

The consolidated financial statements include our accounts and results of operations and those of our wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Revenue Recognition

Our license and collaboration agreements may contain multiple elements, including license and technology access fees, research and development funding, manufacturing revenue, cost-sharing, milestones and royalties. The deliverables under such an arrangement are evaluated under Accounting Standards Codification ("ASC") 605-25, *Multiple-Element Arrangements*. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has "stand-alone value" to the customer. The arrangement's consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables.

Other than for our collaboration with Healios that has remaining deliverables, we have recognized the full amount of license fees under our collaboration agreements as contract revenue under ASC 605-25 as of December 31, 2016, since the performance periods for our multiple element arrangements have concluded. For agreements entered into prior to January 1, 2011 and not materially modified thereafter (such as RTI Surgical, Inc. ("RTI") and Bristol-Myers Squibb Company ("Bristol-Myers Squibb") contract revenue), in which the performance period has concluded, we applied our prior accounting policy with respect to such arrangements under ASC 605-S25, issued as Staff Accounting Bulletin ("SAB") Topic 13. The events triggering any future contingent milestone payments from our Bristol-Myers Squibb arrangement were determined to be non-substantive and revenue is recognized in the period that the triggering event occurs, and the remaining potential commercial milestones from our RTI collaboration are recognized when earned. Contract revenue in 2016 included \$0.6 million from these collaborations related to these development or commercial milestones.

We recognize revenue, in full, in the period that the milestone is achieved from at-risk, performance milestones that are related to our past performance and determined to be substantive at the inception of the arrangement.

Grant revenue consists of funding under cost reimbursement programs primarily from federal and non-profit foundation sources for qualified research and development activities performed by us, and as such, are not based on estimates that are susceptible to change. Such amounts are invoiced and recorded as revenue as tasks are completed.

We recognize contract revenue from royalties relating to the sale by a licensee of the licensed product. Royalty revenue is recognized on an accrual basis in accordance with the substance of the relevant agreement and based on the reports from the licensee to enable calculation of the royalty due.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents are primarily invested in money market funds and commercial paper. The carrying amount of our cash equivalents approximates fair value due to the short maturity of the investments.

Cash used in investing activities excluded \$0.1 million of accrued capital expenditures in 2016.

Investments in Available-for-Sale Securities

We determine the appropriate classification of investment securities, if any, at the time of purchase and re-evaluate such designation as of each balance sheet date. Our investments typically consist of United States government obligations, U.S. government-backed municipal bonds and bank certificates of deposit, which are classified as available-for-sale and are valued based on market prices for similar assets using third party certified pricing sources. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of applicable tax, reported as a component of accumulated other comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization or accretion is included in interest income. At December 31, 2016, we had no available-for-sale securities. Realized gains and losses for the year on available-for-sale securities were insignificant and are included in interest income. The cost of securities sold is based on the specific identification method. Interest earned on securities classified as available-for-sale is included in interest income.

Research and Development

Research and development expenditures, which consist primarily of costs associated with external clinical and preclinical study fees, investigational product manufacturing costs and process development costs for manufacturing, personnel costs, legal expenses resulting from intellectual property application and maintenance processes, and laboratory supply and reagent costs, including direct and allocated overhead expenses, are charged to expense as incurred.

Collaborative Arrangements

Collaborative arrangements that involve cost or future profit sharing are reviewed to determine the nature of the arrangement and the nature of the collaborative parties' businesses. The arrangements are also reviewed to determine if one party has sole or primary responsibility for an activity, or whether the parties have shared responsibility for the activity. If responsibility for an activity is shared and there is no principal party, then the related costs of that activity are recognized by us on a net basis in the statement of operations (e.g., total cost less reimbursement from collaborator). If we are deemed to be the principal party for an activity, then the costs and revenues associated with that activity are recognized on a gross basis in the statement of operations. The accounting may be susceptible to change if the nature of a collaborator's business changes. Currently, we have no collaborations accounted for on a net basis.

Clinical Trial Costs

Clinical trial costs are accrued based on work performed by outside contractors that manage and perform the trials, and that manufacture clinical product. We obtain initial estimates of total costs based on enrollment of subjects, project management estimates, manufacturing estimates and other activities. Actual costs are typically charged to us and recognized as the tasks are completed by the contractor, and if we are invoiced based on progress payments as opposed to actual costs, we develop estimates of work completed to date. Accrued clinical trial costs may be subject to revisions as clinical trials progress, and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

Royalties

We may be required to make future royalty payments to certain parties based on product sales under license agreements. We did not pay any royalties during the three-year period ended December 31, 2016. We may also pay sublicense fees from time-to-time in connection with our collaborations.

Long-Lived Assets

Equipment is stated at acquired cost less accumulated depreciation. Laboratory and office equipment are depreciated on the straight-line basis over the estimated useful lives (three to ten years). Leasehold improvements are amortized over the shorter of the lease term or estimated useful life.

Long-lived assets are evaluated for impairment when events or changes in circumstances indicate that the carrying amount of the asset or related group of assets may not be recoverable. If the expected future undiscounted cash flows are less than the carrying amount of the asset, an impairment loss is recognized at that time. Measurement of impairment may be based upon appraisal, market value of similar assets or discounted cash flows.

Proceeds from Insurance

In 2016, our facility sustained flood damage representing both an unusual and infrequent event. We recognized a net insurance recovery gain of \$682,000 that was reported as a separate component of our loss from operations. The nature and financial effect of the event was disclosed in the notes to financial statements. Proceeds from insurance settlements, except for those directly related to investing or financing activities, were recognized as cash inflows from operating activities. The losses related to such an event are recognized as incurred. Since the majority of the damage from the flood was to fully depreciated leasehold improvements, the amount of losses were less than the amount of the insurance proceeds received. Insurance proceeds are recorded to the extent of the losses and then, only if recovery is realized or probable. Any gains in excess of losses are recognized only when the contingencies regarding the recovery are resolved, and the amount is fixed or determinable.

Patent Costs and Rights

Costs of prosecuting and maintaining patents and patent rights are expensed as incurred. We have filed for broad intellectual property protection on our proprietary technologies and have numerous United States and international patents and patent applications related to our technologies.

Warrant Liabilities

We account for common stock warrants as either liabilities or as equity instruments depending on the specific terms of the warrant agreements. Registered common stock warrants that could require cash settlement are accounted for as liabilities. We classify these warrant liabilities on the consolidated balance sheet as non-current liabilities. The warrant liabilities are revalued at fair value at each balance sheet date subsequent to the initial issuance. Changes in the fair market value of the warrants are reflected in the consolidated statement of operations as income or expense from change in fair value of warrants.

Concentration of Credit Risk

Our accounts receivable are generally comprised of amounts due from collaborators and granting authorities and are subject to concentration of credit risk due to the absence of a large number of customers. At December 31, 2016, the majority of our accounts receivable are due from a collaborator. We do not require collateral from these customers.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Stock-Based Compensation

We recognize stock-based compensation expense on the straight-line method and use a Black-Scholes option-pricing model to estimate the fair value of option awards. The expected term of options granted represent the period of time that option grants are expected to be outstanding. We use the “simplified” method to calculate the expected life of option grants given our limited history of exercise activity and determine volatility by using our historical stock volatility. The fair value of our restricted stock units are equal to the closing price of our common stock on the date of grant and is expensed over the vesting period on a straight-line basis. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons that receive equity awards.

Options may be exercised for cash or by a cashless exercise that is permitted under certain conditions. In the event of a cashless exercise, we retain the number of shares equivalent to the exercise cost based on the market value at the time of exercise, and issue the net number of shares to the holder.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. If actual forfeitures vary from the estimate, we recognize the difference in compensation expense in the period the actual forfeitures occur or when options vest.

All of the aforementioned estimates and assumptions are evaluated on a quarterly basis and may change as facts and circumstances warrant. Changes in these assumptions can materially affect the estimate of the fair value of our share-based payments and the related amount recognized in our financial statements.

The following weighted-average input assumptions were used in determining the fair value of the Company’s stock options:

| | December 31, | | |
|-------------------------|--------------|------------|------------|
| | 2016 | 2015 | 2014 |
| Volatility | 70.3% | 83.9% | 104.0% |
| Risk-free interest rate | 1.5% | 2.1% | 2.1% |
| Expected life of option | 6.18 years | 6.14 years | 6.09 years |
| Expected dividend yield | 0.0% | 0.0% | 0.0% |

Income Taxes

Deferred tax liabilities and assets are determined based on the differences between the financial reporting and tax basis of assets and liabilities and are measured using the tax rate and laws currently in effect. We evaluate our deferred income taxes to determine if a valuation allowance should be established against the deferred tax assets or if the valuation allowance should be reduced based on consideration of all available evidence, both positive and negative, using a “more likely than not” standard.

We had no liability for uncertain income tax positions as of December 31, 2016 and 2015. Our policy is to recognize potential accrued interest and penalties related to the liability for uncertain tax benefits, if applicable, in income tax expense. Net operating loss and credit carryforwards since inception remain open to examination by taxing authorities, and will for a period post utilization.

Net Loss per Share

Basic and diluted net loss per share have been computed using the weighted-average number of shares of common stock outstanding during the period. For each reporting period, we evaluate the income from our warrant liabilities and consider whether it results in a potentially dilutive effect to net loss per share. For the years ended December 31, 2015 and 2014, we had such a dilutive effect related to our warrants with an exercise price of \$1.01, which are included in the table below. Any such warrants are then omitted from the subsequent following table of instruments that were excluded from the calculation of diluted net loss per share. The table below reconciles the net loss and the number of shares used to calculate basic and diluted net loss per share for the years ended December 31, 2016, 2015 and 2014, in thousands.

| | Year ended December 31, | | |
|---|-------------------------|-------------------|-------------------|
| | 2016 | 2015 | 2014 |
| Numerator: | | | |
| Net loss and comprehensive loss | \$(15,337) | \$(16,422) | \$(22,082) |
| Less: income from change in fair value of warrants | — | (332) | (2,141) |
| Net loss attributable to common stockholders used to calculate diluted net loss per share | \$(15,337) | \$(16,754) | \$(24,223) |
| Denominator: | | | |
| Weighted-average shares outstanding - basic | 84,715 | 82,144 | 76,955 |
| Potentially dilutive common shares outstanding: | | | |
| Warrants | — | 707 | 1,586 |
| Weighted-average shares used to calculate diluted net loss per share | 84,715 | 82,851 | 78,541 |
| Basic – net loss per share | \$ (0.18) | \$ (0.20) | \$ (0.29) |
| Dilutive – net loss per share | \$ (0.18) | \$ (0.20) | \$ (0.31) |

We have outstanding options, restricted stock units and warrants that are not used in the calculation of diluted net loss per share because to do so would be antidilutive. The following instruments were excluded from the calculation of diluted net loss per share because their effects would be antidilutive:

| | Year ended December 31, | | |
|------------------------|-------------------------|-------------------|-------------------|
| | 2016 | 2015 | 2014 |
| Stock options | 9,236,228 | 7,052,642 | 6,383,457 |
| Restricted stock units | 1,201,159 | 1,069,100 | 1,889,267 |
| Warrants | 1,893,527 | 2,810,000 | 6,310,000 |
| | <u>12,330,914</u> | <u>10,931,742</u> | <u>14,582,724</u> |

Recently Issued Accounting Standards

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation - Improvements to Employee Share-Based Payment Accounting*, which involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Under the new standard, income tax benefits and deficiencies are to be recognized as income tax expense or benefit in the income statement and the tax effects of exercised or vested awards should be treated as discrete items in the reporting period in which they occur. An entity should also recognize excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. Excess tax benefits should be classified along with other income tax cash flows as an operating activity. In regards to forfeitures, the entity may make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures when they occur. This ASU is effective for fiscal years beginning after December 15, 2016 including interim periods within that reporting period, with early adoption permitted, provided that all amendments are adopted in the same period. We adopted this ASU in the first quarter of 2017, electing to account for forfeitures when they occur, and the adoption resulted in the recognition of \$0.2 million of additional expense in the first quarter of 2017.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to put most leases on their balance sheets, but recognize expenses on their income statements in a manner similar to current accounting practice. Under the guidance, lessees initially recognize a lease liability for the obligation to make lease payments and a right-of-use (“ROU”) asset for the right to use the underlying asset for the lease term. The lease liability is measured at the present value of the lease payments over the lease term. The ROU asset is measured at the lease liability amount, adjusted for lease prepayments, lease incentives received and the lessee’s initial direct costs. The guidance is effective for the annual and interim periods beginning after December 15, 2018, with early adoption permitted. We have not elected to early adopt this ASU in 2017 and are in the process of evaluating the impact the new guidance will have on our consolidated financial statements upon adoption.

In November 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2015-17, *Balance Sheet Classification of Deferred Taxes*, which amends the existing guidance to require that deferred income tax liabilities and assets be classified as noncurrent in a classified balance sheet and eliminates the prior guidance, which required an entity to separate deferred tax liabilities and assets into a current amount and a noncurrent amount in a classified balance sheet. The amendments in this ASU are effective for financial statements for annual periods and interim periods within those annual periods beginning after December 15, 2016, with early adoption permitted, and the new guidance can be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. We adopted this ASU in the first quarter of 2016 on a prospective basis and, therefore, the adoption did not impact prior period financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, which establishes management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and, if so, to provide related footnote disclosures. ASU 2014-15 provides a definition of the term “substantial doubt” and requires an assessment for a period of one year after the date that the financial statements are issued or available to be issued. Management will also be required to evaluate and disclose whether it has plans to alleviate that doubt. The guidance became effective for us the annual periods ending after December 15, 2016, i.e., for year-end 2016 and interim periods thereafter, and as such, we adopted ASU 2014-15 in the fourth quarter of 2016. The adoption resulted in our adding a liquidity disclosure to the footnotes to our financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. ASU 2014-09 requires an entity to recognize revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, the amendment provides five steps that an entity should apply when recognizing revenue. The amendment also specifies the accounting of some costs to obtain or fulfill a contract with a customer and expands the disclosure requirements around contracts with customers. An entity can either adopt this amendment retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the update recognized at the date of initial application. In August 2015, the FASB issued ASU 2015-14, which delays the effective date by one year, making the new standard effective for annual and interim reporting periods beginning after December 15, 2017. Early adoption is permitted for annual reporting periods beginning after December 15, 2016. We have not elected to early adopt this ASU in 2017 and are in the process of evaluating, but have not determined, the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements upon adoption in 2018. We intend to provide more detail on our analysis when available.

C. Equipment

| | December 31, | |
|--|-----------------|-----------------|
| | 2016 | 2015 |
| Equipment consists of (in thousands): | | |
| Laboratory equipment | \$ 6,196 | \$ 6,232 |
| Office equipment and leasehold improvements | 3,040 | 2,691 |
| Process development equipment not yet in service | 965 | — |
| | 10,201 | 8,923 |
| Accumulated depreciation | (7,596) | (7,788) |
| | <u>\$ 2,605</u> | <u>\$ 1,135</u> |

In 2016 and 2015, we disposed of approximately \$0.6 million and \$0.2 million, respectively, of obsolete laboratory equipment, office equipment and leasehold improvements, all of which were fully depreciated.

D. Financial Instruments

Fair Value Measurements

We classify the inputs used to measure fair value into the following hierarchy:

- Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 Unadjusted quoted prices in active markets for similar assets or liabilities, or unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are observable for the asset or liability.
- Level 3 Unobservable inputs for the asset or liability.

The following table provides a summary of the financial assets and liabilities measured at fair value on a recurring basis as follows: (in thousands):

| Description | Balance as of December 31, 2016 | Fair Value Measurements at December 31, 2016 Using | | |
|---------------------|---------------------------------------|--|---|---|
| | | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Warrant liabilities | \$ 1,004 | \$ — | \$ — | \$ 1,004 |

| Description | Balance as of December 31, 2015 | Fair Value Measurements at December 31, 2015 Using | | |
|---------------------|---------------------------------------|--|---|---|
| | | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Warrant liabilities | \$ 649 | \$ — | \$ — | \$ 649 |

We review and reassess the fair value hierarchy classifications on a quarterly basis. Changes from one quarter to the next related to the observability of inputs in a fair value measurement may result in a reclassification between fair value hierarchy levels. There were no reclassifications for all periods presented.

The estimated fair value of warrants accounted for as liabilities, representing a level 3 fair value measure, was determined on the issuance date and subsequently marked to market at each financial reporting date. We use the Black-Scholes valuation model to value the warrant liabilities at fair value. Beginning in 2013, we estimated the fair value using the expected volatility based on our historical volatility for warrants. The warrants below, however, which expire in 2017, were issued prior to 2013, and used the historical volatilities of comparable companies from a representative peer group selected based on industry and market capitalization in estimating fair value. The fair value of these warrants was determined using probability weighted-average assumptions, and the following inputs were used at December 31, 2016:

| | Expected Volatility | Risk-Free Interest Rate | Expected Life |
|---|---------------------|-------------------------|---------------|
| Warrants with one year or less remaining term | 60.81% | 0.51% | 0.2 year |

A roll-forward of fair value measurements using significant unobservable inputs (Level 3) for the warrants is as follows (in thousands):

| | Year ended December 31, 2016 |
|----------------------------------|---------------------------------|
| Balance January 1, 2016 | \$ 649 |
| Settlements from exercise | (202) |
| Expense for the period | 557 |
| Balance December 31, 2016 | \$ 1,004 |

Financing Arrangements

We lease office and laboratory space under operating leases. The lease for our corporate offices and laboratories began in 2000 and currently expires in March 2018, and we have the option to renew annually through 2019. Our rent is \$267,000 per year and our rental rate has not changed since the lease inception in 2000. Also, we lease office and laboratory space for our Belgian subsidiary, which currently expires in July 2017 and includes options to renew annually through July 2022, with annual rent of approximately \$172,000, subject to adjustments based on an inflationary index.

Aggregate rent expense was approximately \$465,000, \$467,000 and \$517,000 in 2016, 2015 and 2014, respectively. The future annual minimum lease commitments at December 31, 2016 are approximately \$371,000 for 2017, \$86,000 for 2018 and \$8,000 for 2019.

In 2012, we entered into an arrangement with the Global Cardiovascular Innovation Center (“GCIC”), and the Cleveland Clinic Foundation in which we were entitled to proceeds of up to \$500,000 in the form of a forgivable loan to fund certain preclinical work. Interest on the loan accrued at a fixed rate of 4.25% per annum and was added to the outstanding principal, and the loan carried an expiration date of March 31, 2016. In February 2016, the loan, which had a balance of \$190,000, was forgiven according to its terms based on our achievement of certain milestones.

We paid no interest during the three years ended December 31, 2016.

E. Collaborative Arrangements and Revenue Recognition

Healios

On January 8, 2016, we entered into a license agreement (“Healios Agreement”) with HEALIOS K.K. (“Healios”) to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan and to provide Healios with access to our proprietary MAPC technology for use in its “organ bud” program, initially for transplantation to treat liver disease or dysfunction. Under the agreement, Healios obtained a right to expand the scope of the collaboration to include the exclusive rights to develop and commercialize MultiStem for the treatment of two additional indications in Japan, which include acute respiratory distress syndrome, or ARDS and another indication in the orthopedic area, and to include all indications for the “organ bud” program. Healios is developing and intends to commercialize the MultiStem product in Japan, and we are using commercially reasonable efforts to supply manufactured product to Healios for its clinical trial. In the event that we determine that we are not able to supply product at a defined price or a price otherwise agreeable to Healios, we may notify Healios and grant it a license to make the product solely for use in the licensed field in Japan. In January 2017, we signed a clinical trial supply agreement, which is consistent with the Healios Agreement, in preparation for delivering these planned manufacturing services for Healios’ clinical trial in Japan.

Under the terms of the Healios Agreement, we received a nonrefundable, up-front cash payment of \$15 million and if Healios exercises its option to expand the collaboration, we will be entitled to receive a cash payment of \$10 million. Healios may exercise its option to expand the collaboration prior to certain milestone dates that are expected to occur within the next two years.

For the ischemic stroke indication, we may also receive additional success-based development, regulatory approval and sales milestones aggregating up to \$225 million. Such amounts are non-refundable and non-creditable towards future royalties or any other payment due from Healios. We will also receive tiered royalties on net product sales, starting in the low double-digits and increasing incrementally into the high teens, depending on net sales levels. Additionally, we will receive payments for product supplied to Healios for ischemic stroke.

[Table of Contents](#)

If Healios exercises the option to expand the collaboration to include ARDS and another indication in the orthopedic area, we would be entitled to receive royalties from product sales and success-based development, regulatory approval and sales milestones, as well as payments for product supply related to the additional indications covered by the option.

For the “organ bud” product, we are entitled to receive a fractional royalty percentage on net sales of the “organ bud” products and payments for manufactured product supplied to Healios. Additionally, we have a right of first negotiation for commercialization of an “organ bud” product in North America, with such right expiring on the later of (i) the date five years from the effective date of the Healios Agreement and (ii) 30 days after authorization to initiate clinical studies on an “organ bud” product under the first investigational new drug application or equivalent in Japan, North America or the European Union.

The Healios Agreement will expire automatically when there are no remaining intellectual property rights subject to the license. In the event that Healios does not move the program forward, the development and commercialization rights would revert to us.

To determine the appropriate accounting for the license agreement, we evaluated the Healios Agreement and related facts and circumstances, focusing in particular on the rights and obligations of the arrangement. We determined that our obligations under the Healios Agreement represent multiple deliverables. For deliverables with standalone value, we account for these as separate units of accounting. We allocate the overall consideration of the arrangement that is fixed or determinable, excluding consideration that is contingent upon future deliverables, to the separate units of accounting based on estimated selling prices (as defined in ASC 605-25) of each deliverable.

Given Healios’ ability to sublicense under the Healios Agreement and its ability to conduct the ongoing development efforts, we concluded that the license had stand-alone value at the inception of the arrangement and would be treated as a separate unit of accounting, noting that there was no general right of return associated with the license. Further, the preclinical and clinical manufacturing services and certain near-term regulatory advisory services that will be provided to Healios under the Healios Agreement had been determined to have stand-alone value and considered separate units of accounting.

We were unable to establish vendor-specific objective evidence of selling price or third-party evidence for either the license or the services, and thus, instead, allocated the arrangement consideration between the license and the services based on their relative selling prices using a best estimate of selling price (“BESP”). We developed the BESP of the license using a probability weighted, discounted cash flow analysis using the income approach, taking into consideration market assumptions including the estimated development and commercialization timeline, data regarding patient population, discount rate related to our industry, and probability of success using market data for both our industry and therapeutic field. We estimated the BESP of the manufacturing services and certain near-term regulatory advisory services using actual historical experience and best estimates of the cost of obtaining these services at arm’s length from a third-party provider, including an estimated mark-up. As a result of the analysis, we allocated \$15 million to the license, which represents the amount of consideration that is allocable pursuant to the relative selling price and is not contingent upon delivery of additional items under the Healios Agreement. The license was delivered and recognized as revenue in January 2016.

Other contingent deliverables that were not accounted for at the inception of the arrangement, and will not be accounted for until the contingency is resolved, included the potential expansion of the collaboration to include additional indications, and the milestones that are not substantive since they are dependent on the activities of Healios. Further, the Healios arrangement contemplates our providing manufacturing services for commercial product supply, the terms of which are not defined and are to be agreed upon in the future under a separate supply agreement.

Upon the removal of the contingencies associated with each of the potential contingent deliverables, including the expansion fee, milestone payments and/or commercial product supply, we will reevaluate the overall arrangement, including the estimated selling prices and the allocation of the overall consideration of the arrangement, with any changes in estimates accounted for on a prospective basis.

RTI Surgical, Inc.

In 2010, we entered into an agreement with RTI Surgical, Inc. (“RTI”) to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market on an exclusive basis. Under the terms of the agreement, we received a non-refundable license fee in installments and performed certain services that were concluded in 2012, and we are eligible to receive cash payments aggregating up to \$35.5 million upon the successful achievement of certain commercial milestones. We evaluated the nature of the events triggering these contingent payments and concluded that these events were substantive and that revenue would be recognized in the period in which each underlying triggering event occurs. No significant milestone revenue has been recognized as of December 31, 2016. In addition, we began receiving in 2014 tiered royalties on worldwide commercial sales of implants using our technologies based on a royalty rate starting in the mid-single digits and increasing into the mid-teens. Any royalties may be subject to a reduction if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product.

Chugai

In October 2015, we and Chugai Pharmaceutical Co. Ltd. (“Chugai”) agreed to terminate the License Agreement (the “Chugai Agreement”), dated February 28, 2015, between the parties, as a result of an inability to reach an agreement on the modification of the financial terms of the Chugai Agreement and on the development strategy, as proposed by Chugai, of our MultiStem cell therapy for the treatment of ischemic stroke in Japan. Pursuant to the terms of the Chugai Agreement, upon termination, we regained all rights for developing our stem cell technologies and products for ischemic stroke in Japan, retained the \$10 million non-refundable upfront cash payment from Chugai and Chugai no longer has any license rights or options with respect to our technologies and products. Neither we nor Chugai have any further obligations to each other.

Grant Award

In 2015, we and Cell Therapy Catapult, a not-for-profit center focused on the development of the United Kingdom regenerative medicine industry, were each awarded a grant from Innovate UK as partial support of a Phase 1/2 clinical study evaluating the administration of MultiStem cell therapy to ARDS patients, which is currently enrolling patients. The aggregate grant funding is expected to provide up to £2.0 million (\$2.5 million based on the December 31, 2016 exchange rate) in support over the course of the study, and the funding is received after the costs are incurred. Of the £2.0 million total award, our portion of the grant of £750,000 (\$0.9 million based on the December 31, 2016 exchange rate) is being used primarily to fund the clinical product and related costs. Cell Therapy Catapult is using their grant proceeds of £1.25 million primarily to fund the clinical site costs and their service costs as study coordinators. We recognized approximately \$157,000 and \$130,000 of grant revenue in 2016 and 2015, respectively, in connection with this grant.

F. Capitalization and Warrant Liability

Capitalization

At both December 31, 2016 and 2015, we had 150.0 million shares of common stock and 10.0 million shares of undesignated preferred stock authorized. No shares of preferred stock have been issued as of December 31, 2016.

The following shares of common stock were reserved for future issuance:

| | December 31 | |
|---|--------------------------|--------------------------|
| | 2016 | 2015 |
| Stock-based compensation plans | 17,940,618 | 8,838,165 |
| Warrants to purchase common stock — 2011 offering | — | 1,310,000 |
| Warrants to purchase common stock — 2012 offering | 1,893,527 | 2,054,893 |
| Warrants to purchase common stock — 2014 offering | — | 1,500,000 |
| | <u>19,834,145</u> | <u>13,703,058</u> |

As of December 31, 2016, the outstanding warrants to purchase shares of common stock had an exercise price of \$1.01 per share and expire in March 2017. As of December 31, 2016, warrants to purchase an aggregate of 2,454,300 shares of common stock have been exercised, resulting in aggregate proceeds of approximately \$2.5 million.

In 2014, we completed a registered direct offering generating net proceeds of approximately \$18.8 million through the issuance of 5,000,000 shares of common stock and immediately exercisable warrants to purchase 1,500,000 shares of common stock with an exercise price of \$4.50 per share that expired in July 2016. The securities were sold in multiples of a fixed combination of one share of common stock and a warrant to purchase 0.30 shares of common stock at an offering price of \$4.10 per fixed combination.

Aspire Capital

We have had an equity purchase arrangement in place with Aspire Capital since 2011, through two-to-three year equity facility agreements, each with similar terms. The current agreement with Aspire Capital was entered into in December 2015 and includes Aspire's commitment to purchase up to an aggregate of \$30.0 million of shares of our common stock over a three-year period. The terms of the 2015 equity facility are similar to the previous arrangements, and we issued 250,000 shares of our common stock to Aspire Capital as a commitment fee in December 2015 and filed a registration statement for the resale of 16,600,000 shares of common stock in connection with the new equity facility. During the years ended December 31, 2016, 2015 and 2014, we sold 2,191,418, 4,023,719, and 250,000 shares, respectively, to Aspire Capital at average prices of \$1.84, \$2.58 and \$3.78 per share, respectively. As of December 31, 2016, we have received proceeds of approximately \$28.8 million in aggregate under the Aspire equity purchase agreements since its inception in 2011.

Warrant Liabilities

The warrants issued in the January 2014 registered direct offering that are now expired contained a provision for a cash payment in the event that the shares are not delivered to the holder within two trading days, which never occurred. The warrants issued in both the March 2012 private placement and the February 2011 registered direct offering, which are now expired, each contained a provision for net cash settlement in the event of a fundamental transaction (e.g., merger, sale of substantially all assets, tender offer, or share exchange). If a fundamental transaction occurs in which the consideration issued consists of all cash or stock in a non-public company, then the warrant holder has the option to receive cash equal to a Black Scholes value of the remaining unexercised portion of the warrant. Further, the March 2012 warrants include price protection in the event we sell stock below the exercise price, as defined, and the exercise price was reduced in February 2013 to \$1.01 per share as a result of the October 2012 public offering.

The warrants have been classified as liabilities, as opposed to equity, due to the potential adjustment to the exercise price that could result upon late delivery of the shares or potential cash settlement upon the occurrence of certain events as described above, and are recorded at their fair values at each balance sheet date.

G. Stock-Based Compensation

We have two incentive plans that authorized an aggregate of 21,500,000 shares of common stock for awards to employees, directors and consultants. These equity incentive plans authorize the issuance of equity-based compensation in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units, and other stock-based awards to qualified employees, directors and consultants. As of December 31, 2016, a total of 3,559,382 shares of common stock have been issued under our equity incentive plans.

As of December 31, 2016, a total of 7,503,231 shares were available for issuance under our equity compensation plans, and stock-based awards to purchase 10,437,387 shares of common stock were outstanding. We recognized \$2,868,000, \$2,929,000 and \$2,605,000 of stock-based compensation expense in 2016, 2015 and 2014, respectively.

Stock Options

The weighted average fair value of options granted in 2016, 2015 and 2014 was \$1.35, \$0.94 and \$1.29 per share, respectively. The total fair value of options vested during 2016, 2015 and 2014 was \$1,662,000, \$1,225,000 and \$940,000, respectively. At December 31, 2016, total unrecognized estimated compensation cost related to unvested stock options was approximately \$4,092,000, which is expected to be recognized by mid-2020 using the straight-line method. The weighted average contractual life of unvested options at December 31, 2016 was 8.96 years. The aggregate intrinsic value of fully vested option shares and option shares expected to vest as of December 31, 2016 was \$153,000.

A summary of our stock option activity and related information is as follows:

| | Number of Options | Weighted Average Exercise Price |
|----------------------------------|------------------------------|--|
| Outstanding January 1, 2014 | 5,129,579 | \$ 3.72 |
| Granted | 1,420,800 | 1.68 |
| Exercised | (103,481) | 1.75 |
| Forfeited / Terminated / Expired | (63,441) | 1.98 |
| Outstanding December 31, 2014 | 6,383,457 | 3.31 |

| | Number of Options | Weighted Average Exercise Price |
|--|----------------------|--|
| Granted | 1,215,296 | 1.31 |
| Exercised | (32,439) | 1.60 |
| Forfeited / Expired | (513,672) | 2.34 |
| Outstanding December 31, 2015 | 7,052,642 | 3.05 |
| Granted | 2,840,000 | 2.13 |
| Exercised | (164,827) | 1.56 |
| Forfeited / Expired | (491,587) | 3.57 |
| Outstanding December 31, 2016 | 9,236,228 | \$ 2.76 |
| Vested during 2016 | 1,332,571 | \$ 1.72 |
| Vested and exercisable at December 31, 2016 | 5,968,199 | \$ 3.22 |

| Exercise Price | December 31, 2016 | | | | | |
|----------------|-------------------------|---|--|--------------------------------|---|--|
| | Options Outstanding | | | Options Vested and Exercisable | | |
| | Number of Options | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number of Options | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price |
| \$1.01 – 1.91 | 4,003,376 | 7.44 | \$ 1.58 | 2,686,969 | 7.06 | \$ 1.59 |
| \$2.09 – 3.84 | 2,499,852 | 8.92 | \$ 2.24 | 550,230 | 6.99 | \$ 2.42 |
| \$4.00 – 5.28 | 2,733,000 | 0.54 | \$ 4.98 | 2,731,000 | 0.54 | \$ 4.98 |
| | 9,236,228 | | | 5,968,199 | | |

Restricted Stock Units

A summary of our restricted stock unit activity and related information is as follows:

| | Number of Restricted Stock Units | Weighted Average Fair Value |
|--|---|-----------------------------------|
| Outstanding January 1, 2014 | 2,449,346 | \$ 1.71 |
| Granted | 460,112 | 1.65 |
| Vested-common stock issued | (1,013,446) | 1.71 |
| Forfeited / Expired | (6,745) | 1.68 |
| Outstanding December 31, 2014 | 1,889,267 | 1.70 |
| Granted | 455,776 | 1.28 |
| Vested-common stock issued | (1,032,979) | 1.69 |
| Forfeited / Expired | (242,964) | 1.62 |
| Outstanding December 31, 2015 | 1,069,100 | 1.55 |
| Granted | 933,552 | 2.19 |
| Vested-common stock issued | (732,720) | 1.71 |
| Forfeited / Expired | (68,773) | 1.90 |
| Outstanding December 31, 2016 | 1,201,159 | \$ 1.92 |
| Vested/Issued cumulative at December 31, 2016 | 3,257,323 | \$ 1.71 |

The total fair value of restricted stock units vested during 2016, 2015 and 2014 was \$1,255,000, \$1,773,000 and \$1,734,000, respectively. At December 31, 2016, total unrecognized estimated compensation cost related to unvested restricted stock units was approximately \$2,222,000, which is expected to be recognized by mid-2020 using the straight-line method.

H. Income Taxes

At December 31, 2016, we had U.S. federal net operating loss and research and development tax credit carryforwards of approximately \$113,080,000 and \$5,842,000, respectively. Such operating losses and tax credits may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2020 and 2036. We also had foreign net operating loss carryforwards and foreign tax credit carryforwards of approximately \$14,863,000 and \$175,000, respectively. Such foreign net operating loss carryforwards do not expire and foreign tax credit carryforwards will expire between 2017 and 2021. We also had state and city net operating loss carryforwards aggregating approximately \$57,881,000. Such operating losses may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2017 and 2036.

The utilization of net operating loss and tax credit carryforwards generated prior to October 2012 (the “Section 382 Limited Attributes”) is substantially limited under Section 382 of the Internal Revenue Code of 1986, as amended, as a result of our equity offering that occurred in October 2012. We generated U.S. federal net operating loss carryforwards of \$76,420,000, research and development tax credits of \$5,842,000, and state and local net operating loss carryforwards of \$56,919,000 since 2012. We will update our analysis under Section 382 prior to using these attributes.

A reconciliation of the Federal statutory income tax rate to our effective tax rate is as follows:

| | Percent of Income before Income Taxes | |
|---|--|---------|
| | 2016 | 2015 |
| Statutory Federal income tax rate | 34.0% | 34.0% |
| State income taxes - net of Federal tax benefit | 0.8% | 1.5% |
| Other permanent differences | (8.1%) | (3.5)% |
| Valuation allowances | (37.0%) | (40.2%) |
| Research and development - U.S. | 10.3% | 8.2% |
| Research and development - Foreign | 0.2% | 0.2% |
| Effective tax rate for the year | 0.2% | 0.2% |

Significant components of our deferred tax assets are as follows (in thousands):

| | December 31, | |
|---|--------------|-----------|
| | 2016 | 2015 |
| Net operating loss carryforwards | \$ 44,929 | \$ 40,215 |
| Research and development credit carryforwards | 6,017 | 4,454 |
| Compensation expense | 2,735 | 3,300 |
| Other | 1,266 | 1,129 |
| Total deferred tax assets | 54,947 | 49,098 |
| Valuation allowance for deferred tax assets | (54,772) | (48,921) |
| Net deferred tax assets | \$ 175 | \$ 177 |

Because of our cumulative losses, substantially all of the deferred tax assets have been fully offset by a valuation allowance. We have not paid income taxes for the three-year period ended December 31, 2016. In 2016, 2015 and 2014, we recognized a refundable tax benefit related to research and development credits associated with a foreign subsidiary.

I. Profit Sharing Plan and 401(k) Plan

We have a profit sharing and 401(k) plan that covers substantially all employees and allows for discretionary contributions by us. We make employer contributions to this plan, and the expense was approximately \$339,000 in 2016, \$314,000 in 2015, and \$284,000 in 2014.

J. Subsequent and Other Events

Equity Offering

In February 2017, we completed a public offering generating net proceeds of approximately \$20.9 million through the issuance of 22,772,300 shares of common stock at an offering price of \$1.01 per share.

Evaluation & Option Agreement

In January 2017, we received an option fee related to an agreement that was entered into in December 2016 with a global leader in the animal health business segment to evaluate our cell therapy technology for application in an animal health area. Under the terms of the agreement, we received the payment in exchange for an exclusive period to evaluate our cell therapy technology with an option to negotiate for a license for the development and commercialization of the technology for this animal health area.

K. Quarterly Financial Data (unaudited)

The following table presents quarterly data for the years ended December 31, 2016 and 2015, in thousands, except per share data:

| | 2016 | | | | |
|--|---------------|----------------|---------------|----------------|------------|
| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter | Full Year |
| Revenues | \$15,458 | \$ 595 | \$ 311 | \$ 983 | \$ 17,347 |
| Net income (loss) | \$ 4,750 | \$(6,956) | \$(6,004) | \$(7,127) | \$(15,337) |
| Basic net income (loss) per common share | \$ 0.06 | \$ (0.08) | \$ (0.07) | \$ (0.08) | \$ (0.18) |
| Diluted net income (loss) per common share | \$ 0.06 | \$ (0.08) | \$ (0.07) | \$ (0.10) | \$ (0.18) |

| | 2015 | | | | |
|--|---------------|----------------|---------------|----------------|------------|
| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter | Full Year |
| Revenues | \$ 731 | \$ 216 | \$ 396 | \$10,605 | \$ 11,948 |
| Net income (loss) | \$(12,482) | \$(1,035) | \$(6,497) | \$ 3,592 | \$(16,422) |
| Basic net income (loss) per common share | \$ (0.16) | \$ 0.01 | \$ (0.08) | \$ 0.04 | \$ (0.20) |
| Diluted net income (loss) per common share | \$ (0.16) | \$ (0.05) | \$ (0.08) | \$ 0.04 | \$ (0.20) |

Due to the effect of quarterly changes to outstanding shares of common stock and weightings, the annual loss per share will not necessarily equal the sum of the respective quarters.

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: An evaluation was carried out under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this annual report on Form 10-K. Based on that evaluation, these officers have concluded that as of December 31, 2016, our disclosure controls and procedures are effective.

Management's report on internal control over financial reporting: Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of internal control over financial reporting based on the 2013 framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation under the 2013 framework in Internal Control — Integrated Framework, management concluded that our internal control over financial reporting was effective as of December 31, 2016. The effectiveness of our internal control over financial reporting as of December 31, 2016 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report, which is included in Item 8 of this annual report on Form 10-K and incorporated herein by reference.

Changes in internal control: During the fourth quarter of 2016, there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On January 11, 2017, the Board of Directors of the Company, based upon the recommendation of the Compensation Committee of the Board of Directors of the Company, approved a cash bonus incentive plan (the "Plan") for the year ending December 31, 2017 for the named executive officers of the Company. The Plan provides that each participant is eligible to earn a bonus during the award term of January 1, 2017 through December 31, 2017. The Plan provides for the following target bonus percentages of the named executive officer's salary during the award term, weighted as set forth below on the achievement of specified corporate goals, with the remainder based on individual/functional performance. The corporate goals include advancing the Company's clinical programs for MultiStem, executing against the established operating plan and capital acquisition objectives, and advancement of strategic partnership and program activities. There is no formally adopted plan document for the Plan.

| <u>Title</u> | <u>Target Bonus</u> | <u>Weighting on Corporate Goals</u> |
|---|---------------------|-------------------------------------|
| Chief Executive Officer | 60% | 100% |
| President & Chief Operating Officer | 45% | 80% |
| Executive Vice President & Chief Scientific Officer | 45% | 80% |
| Senior Vice President of Finance | 35% | 60% |

A summary of the plan is attached to this annual report on Form 10-K as Exhibit 10.42 and is hereby incorporated herein by reference thereto.

PART III**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The persons listed below are the directors and executive officers of the Company as of March 10, 2017.

| <u>Name</u> | <u>Age</u> | <u>Current Position and Office</u> |
|-----------------------------------|------------|---|
| Gil Van Bokkelen, Ph.D. | 56 | Chief Executive Officer, Chairman and Director |
| William (B.J.) Lehmann, Jr., J.D. | 51 | President and Chief Operating Officer |
| John J. Harrington, Ph.D. | 49 | Chief Scientific Officer, Executive Vice President and Director |
| Laura K. Campbell, CPA | 53 | Senior Vice President of Finance |
| Lee E. Babiss, Ph.D. | 61 | Director (Lead Director) |
| Jordan S. Davis | 55 | Director |
| Ismail Kola, Ph.D. | 60 | Director |
| Lorin J. Randall | 73 | Director |
| Jack L. Wyszomierski | 61 | Director |

Executive Officers and Directors

Gil Van Bokkelen, 56. Dr. Van Bokkelen has served as our Chief Executive Officer and Chairman since August 2000. Dr. Van Bokkelen co-founded Athersys in 1995 and has served as Chief Executive Officer and Director since the Company's founding. Prior to May 2006, he also served as the Company's President. Dr. Van Bokkelen is also the Chairman of the Board of Governors for the National Center for Regenerative Medicine. He served as the Chairman of the Alliance for Regenerative Medicine from 2010 through 2012, a Washington D.C. based consortium of companies, patient advocacy groups, disease foundations, and clinical and research institutions that are committed to the advancement of the field of regenerative medicine, and served *ex officio* from 2013 to 2014. He has served on a number of other boards, including the Biotechnology Innovation Organization's ECS board of directors (from 2001 to 2004, and from 2008 to present). He received his Ph.D. in Genetics from Stanford University School of Medicine, his B.A. in Economics from the University of California at Berkeley, and his B.A. in Molecular Biology from the University of California at Berkeley.

Dr. Van Bokkelen brings to the Board leadership, extensive business, operating, financial and scientific experience, and tremendous knowledge of our Company and the biotechnology industry. Dr. Van Bokkelen also brings his broad strategic vision for our Company to the Board of Directors and his service as the Chairman and Chief Executive Officer of Athersys creates a critical link between management and the Board, enabling the Board to perform its oversight function with the benefit of management's perspectives on the business. In addition, having the Chief Executive Officer, and Dr. Van Bokkelen, in particular, on our Board of Directors provides our Company with ethical, decisive and effective leadership.

John J. Harrington, 49. Dr. Harrington co-founded Athersys in 1995 and has served as our Chief Scientific Officer, Executive Vice President and Director since our founding. Dr. Harrington led the development of the RAGE[®] technology, as well as its application for gene discovery, drug discovery and commercial protein production applications. He is a listed inventor on over 20 issued or pending United States patents, has authored numerous scientific publications, and has received numerous awards for his work, including being named one of the top international young scientists by MIT Technology Review in 2002. Dr. Harrington has overseen the therapeutic product development programs at Athersys since their inception, and is also focused on the clinical development and manufacturing of MultiStem[®]. During his career, he has also held positions at Amgen and Scripps Clinic. He received his B.A. in Biochemistry and Cell Biology from the University of California at San Diego and his Ph.D. in Cancer Biology from Stanford University.

Dr. Harrington's scientific experience and deep understanding of our Company, combined with his drive for innovation and excellence, position him well to serve on the Board of Directors.

Executive Officers

William (BJ) Lehmann, Jr., J.D., 51. Mr. Lehmann joined Athersys in September 2001 and has served as our President and Chief Operating Officer since June 2006. Prior to that time, Mr. Lehmann was Athersys' Executive Vice President of Corporate Development and Finance from August 2002 until June 2006, when he became Athersys' President and Chief Operating Officer. From 1994 to 2001, Mr. Lehmann was with McKinsey & Company, Inc., an international management consulting firm, where he worked extensively with new technology and service-based businesses in the firm's Business Building practice. Prior to joining McKinsey, he worked at Wilson, Sonsini, Goodrich & Rosati, a Silicon Valley law firm, and worked with First Chicago Corporation, a financial institution. Mr. Lehmann received his J.D. from Stanford University, his M.B.A. from the University of Chicago, and his B.A. from the University of Notre Dame.

Laura K. Campbell, CPA, 53. Ms. Campbell joined Athersys in January 1998 and has served as our Senior Vice President of Finance since January 2016. Ms. Campbell joined Athersys initially as Controller, followed by Director of Finance, Senior Director of Finance, and Vice President of Finance, and currently serves as Senior Vice President of Finance. Prior to joining Athersys, she was at Ernst & Young LLP, a public accounting firm, for 11 years in the firm's audit practice. During her tenure with Ernst & Young LLP, Ms. Campbell specialized in entrepreneurial services and the biotechnology industry sector and participated in several initial public offerings. Ms. Campbell received her B.S., with distinction, in Business Administration from The Ohio State University.

Directors

Lee E. Babiss, 61. Dr. Babiss has served as Lead Director since October 2013 and a Director since August 2010. Dr. Babiss is currently Chief Executive Officer of X-Rx, Inc., a majority-owned subsidiary of The Carlyle Group and Hellman & Friedman, Inc., which is a biotechnology company focused on the rapid and cost-effective discover and development of small molecule medicines, where he has served since 2012. Prior to his appointment at X-Rx, Dr. Babiss was the Chief Scientific Officer and Executive Vice President of Discovery Innovation of PPD, Inc., a clinical research organization, where he served from February 2010 to 2016. Dr. Babiss was formerly President and Director of Global Pharmaceutical Research at Roche, a pharmaceutical company, from 1998 until his appointment at PPD, Inc. Prior to Roche, Dr. Babiss spent seven years with Glaxo, Inc., now GlaxoSmithKline, a pharmaceutical company, where he held senior positions, including Vice President of Biological Sciences and Genetics. Dr. Babiss received his doctorate in Microbiology from Columbia University and completed his postdoctoral fellowship at the Rockefeller University, where he served as an assistant and associate professor. Dr. Babiss has received numerous fellowship awards and grants and serves on several scientific advisory committees and boards. Dr. Babiss has published over 60 peer-reviewed scientific papers.

Dr. Babiss' brings over 20 years of experience developing and leading research and development programs. His strategic leadership and product development knowledge provide a valuable perspective to the Board.

Jordan S. Davis, 55. Mr. Davis previously served as our Director from June 2007 until June 2010. Mr. Davis is a Managing Partner of Radius, a venture capital firm focused on health and life sciences companies, which he co-founded in 1997. Mr. Davis has served on numerous public and private company boards and currently serves on the board of directors of Endogastric Solutions, Inc., and Tactile Systems Technology, Inc. (NASDAQ: TCMD) since 2012, where he is a member of the compensation and compliance committees. He is also a member of the board of directors and chairman of the audit committee of HealthCorps, a charitable organization engaged in educating youth on nutrition, exercise and mental resilience. Mr. Davis was a co-founder of Cambridge Heart, Inc., a medical technology company that developed and commercialized a device to non-invasively identify patients at risk of sudden cardiac death, and Voxware, Inc., a speech technology company and early entrant in the VoIP market, both of which completed initial public offerings in 1996. Mr. Davis earned an M.B.A. from the Kellogg School of Management at Northwestern University and a B.A. in Economics from The State University of New York at Binghamton.

Mr. Davis' deep understanding of our Company as a long-term stockholder, knowledge of the industry, experience as a director and extensive investment and capital markets experience brings a unique and valuable perspective to the Board.

Ismail Kola, 60. Dr. Kola has served as a Director since October 2010. Dr. Kola is currently Executive Vice President of UCB S.A. in Belgium, a biopharmaceutical company dedicated to the development of innovative medicines focused on the fields of central nervous system and immunology disorders, and President and Chief Scientific Officer of UCB New Medicines, UCB's discovery research through to proof-of-concept in man organization, since November 2009. Dr. Kola was formerly Senior Vice President, Discovery Research and Early Clinical Research & Experimental Medicine at Schering-Plough Research Institute, the pharmaceutical research arm of Schering-Plough Corporation, a pharmaceutical company, and Chief Scientific Officer at Schering-Plough Corporation, from March 2007 until his appointment at UCB. Prior to Schering-Plough, Dr. Kola held senior positions from January 2003 to March 2007 at Merck, a pharmaceutical company, where he was Senior Vice President and Site Head, Basic Research. From 2000 to 2003, Dr. Kola was Vice President, Research, and Global Head, Genomics Science and Biotechnology, at Pharmacia Corporation, a pharmaceutical company. Prior to his position with Pharmacia, Dr. Kola spent 15 years as Professor of Human Molecular Genetics and was Director of the Centre for Functional Genomics and Human Disease at Monash Medical School in Australia. Dr. Kola received his Ph.D. in Medicine from the University of Cape Town, South Africa, his B.Sc. from the University of South Africa, and his B.Pharm. from Rhodes University, South Africa. Dr. Kola served on the board of directors of Biotie Therapies, Inc. (NASDAQ: BITI) (and previously Synosia, who merged with Biotie) from February 2011 until May 2016, where he served on the compensation committee. Dr. Kola served on the board of directors of Astex Therapeutics (NASDAQ: ASTX) from May 2010 until its sale to Otsuka Pharmaceuticals in October 2013, Ondek Pty Ltd from 2009 to 2011, and Promega Corporation from 2003 to 2007. Dr. Kola has authored 159 technical publications in scientific and medical journals and is the named inventor on at least a dozen patents. Dr. Kola holds Adjunct Professorships of Medicine at Washington University in St. Louis, Missouri, and Monash University Medical School; a Foreign Adjunct Professorship at the Karolinska Institute in Stockholm, Sweden; and was elected William Pitt Fellow at Pembroke College, Cambridge University, UK in 2008. Dr. Kola has also been appointed a Visiting Professor at Oxford University, Nuffield School of Medicine, Oxford UK, since September 2012.

Dr. Kola has led numerous teams that have brought a large number of medicines successfully to the market. Dr. Kola's experience and leadership in taking numerous drugs from the research stage to market or late stage development brings a unique and valuable perspective to our Board.

Lorin J. Randall, 73. Mr. Randall has served as a Director since September 2007. Mr. Randall is an independent financial consultant and previously was Senior Vice President and Chief Financial Officer of Eximias Pharmaceutical Corporation, a development-stage drug development company, from 2004 to 2006. From 2002 to 2004, Mr. Randall served as Senior Vice President and Chief Financial Officer of i-STAT Corporation, a publicly-traded manufacturer of medical diagnostic devices that was acquired by Abbott Laboratories in 2004. From 1995 to 2001, Mr. Randall was Vice President and Chief Financial Officer of CFM Technologies, Inc., a publicly-traded manufacturer of semiconductor manufacturing equipment. Mr. Randall currently serves on the boards of directors of Acorda Therapeutics, Inc. (NASDAQ: ACOR) since 2006, where he serves on the audit committee and is a member of the compliance and nominations and governance committees, and since 2016, Aurinia, Inc. (NASDAQ: AUPH, TSX: AUP), where he serves as chair of the audit committee. He previously served on the boards of directors of Tengion, Inc. (OTCQB: TNGN) from 2008 to 2014, where he served as chairman of the audit committee and a member of the compensation committee, Opexa Therapeutics, Inc. (NASDAQ: OPXA) from 2007 to 2009, where he served as chair of the audit committee, and Nanosphere, Inc. (NASDAQ: NSPH) from 2008 to 2016 where he served as chairman of the board and chairman of the audit committee. Mr. Randall received a B.S. in accounting from The Pennsylvania State University and an M.B.A. from Northeastern University.

Mr. Randall's strong financial and human resources background and his service on the audit and compensation committees of other companies provides expertise to the Board, including an understanding of financial statements, compensation policies and practices, corporate finance, developing and maintaining effective internal controls, accounting, employee benefits, investments and capital markets. These qualities also formed the basis for the Board's decision to appoint Mr. Randall as chairman of the Audit Committee and the Compensation Committee.

Jack L. Wyszomierski, 61. Mr. Wyszomierski has served as a Director since June 2010. From 2004 until his retirement in June 2009, Mr. Wyszomierski served as the Executive Vice President and Chief Financial Officer of VWR International, LLC, a supplier and distributor of laboratory supplies, equipment and supply chain solutions to the global research laboratory industry. From 1982 to 2004, Mr. Wyszomierski held positions of increasing responsibility within the finance group at Schering-Plough Corporation, a pharmaceutical company, culminating with his appointment as Executive Vice President and Chief Financial Officer in 1996. Prior to joining Schering-Plough, he was responsible for capitalization planning at Joy Manufacturing Company, a producer of mining equipment, and was a management consultant at Data Resources, Inc., a distributor of economic data. Mr. Wyszomierski currently serves on the board of directors of Solenis, Inc., a privately held chemicals company since 2014, where he serves as Chair of the Audit Committee and a member of the Compensation Committee, Xoma Corporation (NASDAQ: XOMA) since 2010, where he also serves as chairman of the compensation committee and as a member of the audit committee, Exelixis, Inc. (NASDAQ: EXEL) since 2004, where he serves as chairman of the audit committee, and SiteOne Landscape Supply, Inc. (NYSE: SITE) since 2016, where he also serves on the Audit Committee. Mr. Wyszomierski was also a member of the board of directors and chairman of the audit committee at Unigene Laboratories, Inc. (OTC: UGNE) from 2012 to 2013. Mr. Wyszomierski holds a M.S. in Industrial Administration and a B.S. in Administration, Management Science and Economics from Carnegie Mellon University.

Mr. Wyszomierski's extensive financial reporting, accounting and finance experience and his service on the audit committees of other public companies, as well as his experience in the healthcare and life sciences industries, provides financial expertise to the Board, including an understanding of financial statements, corporate finance, developing and maintaining effective internal controls, accounting, investments and capital markets.

Section 16(a) Beneficial Ownership Reporting Compliance

Based solely on a review of reports of ownership, reports of changes of ownership and written representations under Section 16(a) of the Exchange Act that were furnished to the Company during or with respect to fiscal year 2016 by persons who were, at any time during fiscal year 2016, Directors or officers of the Company or beneficial owners of more than 10% of the outstanding shares of common stock, all filing requirements for reporting persons were met.

Code of Ethics

Athersys has adopted a code of ethics that applies to its principal executive officer, principal financial officer and principal accounting officer. Athersys' code of ethics is posted under the Investors tab of its website at www.athersys.com. Athersys will post any amendments to, or waivers of, its code of ethics that apply to its principal executive officer, principal financial officer and principal accounting officer on its website.

Audit Committee

The Audit Committee is responsible for overseeing the accounting and financial reporting processes of the Company and the audits of the financial statements of the Company. The Audit Committee is also directly responsible for the appointment, compensation, retention and oversight of the work of the Company's independent auditors, including the resolution of disagreements between management and the auditors regarding financial reporting. Additionally, the Audit Committee approves all related-party transactions that are required to be disclosed pursuant to Item 404 of Regulation S-K. The current members of the Audit Committee are Lorin J. Randall, Jordan S. Davis and Jack L. Wyszomierski. The Board of Directors has determined that each of Mr. Randall, Mr. Traub and Mr. Wyszomierski is an "audit committee financial expert," as defined in Item 407(d)(5)(ii) of Regulation S-K, and an "independent director," as defined in the NASDAQ listing standards.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

Executive Summary

This section discusses the principles underlying our executive compensation policies and decisions and the most important factors relevant to an analysis of these policies and decisions. It provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our named executive officers, which include Dr. Gil Van Bokkelen, our Chief Executive Officer, Ms. Laura Campbell, our Senior Vice President of Finance, Mr. William (B.J.) Lehmann, Jr., our President and Chief Operating Officer and Dr. John Harrington, our Executive Vice President and Chief Scientific Officer, and places in perspective the data presented in the compensation tables and narratives that follow.

We are an international biotechnology company that is focused primarily in the field of regenerative medicine. Our MultiStem cell therapy is a patented and proprietary allogeneic stem cell product, is our lead platform product and is currently in later-stage clinical development. Our current clinical development programs are focused on treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, certain pulmonary conditions and other conditions where the current standard of care is limited or inadequate for many patients. As further discussed in this section, our compensation and benefit programs help us attract, retain and motivate individuals who will maximize our business results by working to meet or exceed established company or individual objectives. In addition, we reward our executive officers for meeting certain developmental milestones, such as completing advancements in product candidate development, strategic partnerships or other financial transactions that add to the capital resources of the Company or create value for stockholders.

The following are the highlights of our 2016 compensation and benefit programs:

- increased the base salaries of our named executive officers;
- paid cash incentive compensation to our named executive officers; and
- granted stock options and restricted stock unit awards to our named executive officers under our annual equity compensation program.

The following discussion and analysis of our compensation and benefit programs for 2016 should be read together with the compensation tables and related disclosures that follow this section. This discussion includes forward-looking statements based on our current plans, considerations, expectations and determinations about our compensation program. Actual compensation decisions that we may make for 2017 and beyond may differ materially from our recent past.

Compensation Objectives and Philosophy

Our executive compensation programs are designed to:

- recruit, retain, and motivate executives and employees that can help us achieve our core business goals;

- provide incentives to promote and reward superior performance throughout the organization, which we refer to as Pay for Performance;
- facilitate stock ownership and retention by our executives and other employees; and
- promote alignment between executives and other employees and the long-term interests of stockholders.

The Compensation Committee seeks to achieve these objectives by:

- establishing a compensation program that is market competitive and internally fair;
- linking individual and corporate performance with certain elements of compensation through the use of equity grants, cash performance compensation or other means of compensation, the value of which is substantially tied to the achievement of our Company goals; and
- when appropriate, given the nature of our business, rewarding our executive officers for both Company and individual achievements with one-time performance awards.

At the 2016 Annual Meeting of Stockholders, approximately 88% of the votes cast were voted in favor of the approval of our named executive officer compensation. Our Compensation Committee believes that the stockholder vote reinforces the objectives and philosophy of our executive compensation programs.

Components of Compensation

Our executive compensation program includes the following elements:

- base salary;
- cash incentive compensation;
- long-term equity incentive plan awards; and
- retirement and health and other insurance benefits.

Our Compensation Committee has not adopted any formal or informal policies or guidelines for allocating compensation between long-term and currently paid-out compensation, between cash and non-cash compensation or among different forms of non-cash compensation. We consider competitive practices, relative management level and operating responsibilities of each executive officer when determining the compensation elements to reward his or her ability to impact short-term and long-term results.

Role of the Chief Executive Officer

Historically, our Chief Executive Officer has taken the lead in providing our Board of Directors with advice regarding executive compensation. For 2016, the Compensation Committee considered recommendations from our Chief Executive Officer regarding the compensation for and performance of our executive officers in relation to company-specific strategic goals that were established by the Compensation Committee and approved by the Board of Directors. These achievements related to potential cash incentive compensation payments and salary increases. The Compensation Committee considers the recommendations made by our Chief Executive Officer because of his knowledge of the business and the performance of the other executive officers. The Compensation Committee is not bound by the input it receives from our Chief Executive Officer. Instead, the Compensation Committee exercises independent discretion when making executive compensation decisions. We describe and discuss the particular compensation decisions made by the Compensation Committee regarding the 2016 compensation of our named executive officers below under “Elements of Executive Compensation.”

Role of the Independent Compensation Consultant

From time to time, the Compensation Committee has retained the services of an independent compensation consultant, Arnosti Consulting, Inc., or Arnosti. During 2016, at the request of the Compensation Committee, Arnosti assisted the Compensation Committee in evaluating the base salaries to be paid to named executive officers and the annual equity awards to be granted company-wide. The Company pays the cost for Arnosti’s services. However, the Compensation Committee retains the sole authority to engage, direct or terminate Arnosti’s services. In 2016, the Compensation Committee considered and assessed all relevant factors, including but not limited to, those set forth in Rule 10C-1(b)(4)(i) through (vi) under the Exchange Act, that could give rise to a potential conflict of interest with respect to Arnosti’s work. Based on this review, we are not aware of any conflict of interest that has been raised by the work performed by Arnosti.

Elements of Executive Compensation

Base Salary. We pay base salaries to provide executive officers with a competitive level of financial security. We establish base salaries for our executives based on the scope of their responsibilities, taking into account competitive market compensation paid by other companies for similar positions and peer group benchmark pay. Our peer group consists of eighteen companies with a similar stage of development, market capitalization, and revenues, including Arrowhead Research Corporation, Aviragen Therapeutics Inc., BioTime Inc., Chimerix Inc., Concert Pharmaceuticals Inc., ChemCentryx Inc., Edocyte Inc., GTX Inc., Idera Pharmaceuticals, Medicinova Inc., Osiris Therapeutics Inc., Rigel Pharmaceuticals Inc., Regulus Therapeutics Inc., Sangamo Biosciences Inc., Stemline Therapeutics Inc., Threshold Pharmaceuticals Inc., Verastem Inc. and Vericel Corporation.

Base salaries are generally reviewed annually, with adjustments based on the individual's responsibilities, performance and experience during the year. This review generally occurs each year following an annual review of individual performance.

In general, the Company and the executive team performed well in 2016 against many key goals and objectives, as measured against the metrics of key programmatic achievements (e.g., clinical, regulatory, preclinical and core capability development), business development objectives and operational and financial performance (e.g., budgetary goals, capital acquisition and management), among others. Each executive's performance was evaluated based on the Company's performance as a whole, combined with an evaluation of individual performance against goals and objectives relevant to his or her area of responsibility. Overall, some, but not all corporate goals were achieved in 2016. For example, though a business partnership was put in place and certain regulatory goals were achieved, other clinical trial objectives were not met.

For 2016, the Compensation Committee and the Board of Directors approved an increase in base salary of 2.0% as compared to 2015 for the Chief Executive Officer, an adjustment based on both performance and comparative market data provided to the Compensation Committee by Arnosti. Also, the Compensation Committee and the Board of Directors approved increases for each of the other named executive officer's salary for 2016 as compared to 2015 based primarily on Company performance for the year ended December 31, 2015. The increases were as follows: Mr. Lehmann – 2.0%; Dr. Harrington – 2.0%; and Ms. Campbell – 2.0%. Furthermore, Ms. Campbell was promoted effective January 1, 2016 to Senior Vice President of Finance in recognition of her significant contribution in leading the financial and administrative activities of the Company in a highly effective manner, and her expected ongoing contributions in supporting overall management and related activities within the Company, which resulted in an additional 5.25% increase in her salary related to the promotion.

For 2017, the Compensation Committee and the Board of Directors approved an increase in base salary of 8.4% as compared to 2016 for the Chief Executive Officer, an adjustment based on both performance and comparative compensation data from the peer companies listed above that was provided to the Compensation Committee by Arnosti. Also, the Compensation Committee and the Board of Directors approved increases for each of the other named executive officer's salary for 2017 as compared to 2016 based primarily on Company performance for the year ended December 31, 2015. The increases were as follows: Mr. Lehmann – 3.1%; Dr. Harrington – 3.0%; and Ms. Campbell – 3.1%. The salary information for our named executive officers is summarized below:

| | 2015 | | 2016 | | 2017 | |
|------------------|-------------|------------|-------------|------------|-------------|------------|
| | 2015 Salary | % Increase | 2016 Salary | % Increase | 2017 Salary | % Increase |
| Dr. Van Bokkelen | \$ 475,000 | 1.75% | \$ 484,500 | 2.00% | \$ 525,000 | 8.40% |
| Dr. Harrington | \$ 387,000 | 1.84% | \$ 394,740 | 2.00% | \$ 406,750 | 3.00% |
| Mr. Lehmann | \$ 389,000 | 1.83% | \$ 396,780 | 2.00% | \$ 409,000 | 3.10% |
| Ms. Campbell | \$ 251,750 | 1.81% | \$ 270,000 | 7.25% | \$ 278,500 | 3.10% |

Cash Incentive Compensation. Given the nature of our business, when appropriate, we reward our named executive officers with performance-related compensation. We utilize annual incentive compensation to reward officers and other employees for achieving corporate objectives and for meeting individual annual performance objectives. These objectives relate generally to strategic factors, including advancement of our product candidates, identification and advancement of additional programs or product candidates, establishment and maintenance of key strategic relationships, and to financial factors, including raising capital, adherence to budgets and cash management.

The Compensation Committee recommended and the Board approved a cash incentive compensation program for the year ended December 31, 2016 for our named executive officers. Under the 2016 incentive program, each participant was eligible to earn a target incentive compensation payment of a specified percentage of the named executive officer's salary during the award term, weighted on the achievement of specific corporate goals, with the remainder based on individual/functional performance, as set forth in the following table. The weighting on corporate versus individual/functional performance is related to the relative impact on overall corporate goals and the emphasis and incentives toward departmental performance.

| | Target Amount | Weighted On | |
|------------------|---------------|-----------------|-----------------------------------|
| | | Corporate Goals | Individual/Functional Performance |
| Dr. Van Bokkelen | 60% | 100% | 0% |
| Dr. Harrington | 45% | 80% | 20% |
| Mr. Lehmann | 45% | 80% | 20% |
| Ms. Campbell | 35% | 60% | 40% |

The evaluation of goal achievement is at the discretion of the Compensation Committee and the Board of Directors based on input from the Chief Executive Officer (with respect to the named executive officers other than the Chief Executive Officer). The 2016 corporate goals included program and collaboration goals, including new business development, progress on MultiStem clinical development and cash management objectives. While the overall amount of incentive compensation is tied to predetermined metrics, the Board of Directors has the discretion to adjust any amount ultimately paid under our annual incentive program after good faith consideration of executive officer performance, overall company performance, market conditions and cash availability. We do not have a formally adopted plan document for the 2016 incentive program, although the Compensation Committee recommended and the Board of Directors approved the specific corporate goals, target compensation levels and weightings between corporate and functional performance. The Compensation Committee and the Board of Directors agreed that each of the named executive officers would be entitled to a payment under the 2016 incentive program as a result of individual performance and the achievement of operational and strategic objectives in 2016, specifically the achievement of patient enrollment and regulatory approval goals for the Company's clinical studies, capital management and the receipt of new grant funding, and other core program development and sector leadership goals, resulting in the payment of incentive compensation based on a percentage of such officers' 2016 base salaries as follows:

| | Percentage of Base Salary | Cash Incentive Compensation Paid |
|------------------|---------------------------|----------------------------------|
| Dr. Van Bokkelen | 31.8% | \$ 154,071 |
| Dr. Harrington | 24.5% | \$ 96,632 |
| Mr. Lehmann | 24.3% | \$ 96,417 |
| Ms. Campbell | 19.1% | \$ 51,691 |

For the year ending December 31, 2017, the Compensation Committee recommended and the Board of Directors approved a similar cash incentive compensation plan for our named executive officers, with no changes to the target incentive compensation percentage for our named executive officers from 2016. The 2017 corporate goals include strategic partnership objectives, advancing and achieving clinical development and related support activities for MultiStem, program advancement objectives, and executing against the established operating plan and capital acquisition objectives.

Long-Term Incentive Program. We believe that we can encourage superior long-term performance by our executive officers and employees through encouraging them to own, and assisting them with the acquisition of, our common stock. Our equity compensation plans provide our employees, including named executive officers, with incentives to help align their interests with the interests of our stockholders. We believe that the use of common stock and stock-based awards offers the best approach to achieving our objective of fostering a culture of ownership, which we believe will, in turn, motivate our named executive officers to create and enhance stockholder value. We have not adopted stock ownership guidelines, but our equity compensation plans provide a principal method for our executive officers to acquire equity in our company. The following table reflects the number of shares of Athersys Common Stock owned by our named executive officers as of December 31, 2016:

| | Shares of Common Stock Owned |
|------------------|------------------------------|
| Dr. Van Bokkelen | 764,198 |
| Dr. Harrington | 403,031 |
| Mr. Lehmann | 203,755 |
| Ms. Campbell | 377,297 |

Our equity compensation plans authorize us to grant, among other types of awards, options, restricted stock and restricted stock units, or RSUs, to our employees, Directors and consultants. We award RSUs and stock options to our employees. In June 2016, we amended our long-term equity incentive plan to increase the number of shares available for awards under the plan, among other things. We expect to continue to use equity-based awards as a long-term incentive vehicle because we believe:

[Table of Contents](#)

- equity-based awards align the interests of our executives with those of our stockholders, support a pay-for-performance culture, foster an employee stock ownership culture and focus the management team on increasing value for our stockholders;
- equity-based awards have the potential to increase in value based on our performance and the growth of our stock price;
- equity-based awards help to provide a balance to the overall executive compensation program because, while base salary and our discretionary incentive compensation program focus on short-term performance, equity-based awards that vest over time reward increases in stockholder value over the longer-term; and
- the vesting period of equity-based awards encourages executive retention and efforts to preserve stockholder value.

In 2016, we granted 1,418,016 stock options and 596,992 RSUs to our named executive officers, as well as stock options and RSUs to our other employees. Equity awards are tied to factors such as performance, peer and market analysis, and the total equity ownership level of each named executive officer, and further enhance the retention and long-term stock ownership features of our equity incentive program. In determining the number of stock-based awards to be granted to named executive officers, we review annually our named executive officers' equity ownership positions, and we take into account the individual's scope of responsibility, ability to affect results and stockholder value, anticipated future contributions to increases in stockholder value, and the value of equity-based awards in relation to other elements of the individual named executive officer's total compensation; with an emphasis on scope of responsibility, results and stockholder value. We also review competitive compensation data, an assessment of individual performance, a review of each named executive officer's existing long-term incentives, retention considerations and a subjective determination of the individual's potential to positively impact future stockholder value. Equity-based awards are granted from time to time by the Compensation Committee and the Board of Directors, with input from independent compensation consultants, as appropriate. The following stock option and RSU awards were granted to our named executive officers in June 2016 as part of our program for annual equity-based awards, which vest quarterly over a four-year period:

| | Stock Options | Restricted Stock Units |
|------------------|---------------|------------------------|
| Dr. Van Bokkelen | 500,000 | 225,008 |
| Dr. Harrington | 348,608 | 149,392 |
| Mr. Lehmann | 361,200 | 154,800 |
| Ms. Campbell | 208,208 | 67,792 |

Retirement and Insurance Benefits . Consistent with our compensation philosophy, we maintain benefits for our named executive officers and our employees, including medical, dental, vision, life and disability insurance coverage and the ability to contribute to a 401(k) retirement plan. The named executive officers and employees have the ability to participate in these benefits at the same levels. We make employer contributions to our 401(k) retirement plan and contributed approximately \$339,000 in 2016. We provide such retirement and health insurance benefits to our employees to retain qualified personnel.

In addition, Dr. Van Bokkelen, Dr. Harrington, Mr. Lehmann and Ms. Campbell also receive Company-paid life insurance benefits in the amounts of \$2.0 million for Dr. Van Bokkelen, Dr. Harrington and Mr. Lehmann, and \$1.0 million for Ms. Campbell. These additional life insurance policies are provided to these officers due to their extensive travel requirements and contributions to the Company.

Severance Arrangements

See the disclosure under "Potential Payments Upon Termination or Change of Control" for more information about severance arrangements with our named executive officers. We provide such severance arrangements in order to assure that our executives will focus on the best interests of the business at all times, without undue concern for their own financial security.

Employment Agreements and Arrangements

We believe that entering into employment agreements with each of our named executive officers was necessary for us to attract and retain talented and experienced individuals for our senior level positions. In this way, the employment agreements help us meet the initial objective of our compensation program. Each agreement contains terms and arrangements that we agreed to through arms-length negotiation with our named executive officers. We view these employment agreements as reflecting the minimum level of compensation that our named executive officers require to remain employed with us, and thus the bedrock of our compensation program for our named executive officers. For more details of our employment agreements and arrangements, see the disclosure under "2016 Summary Compensation Table."

General Tax Deductibility of Executive Compensation

We structure our compensation program to comply with Internal Revenue Code Section 162(m). Under Section 162(m) of the Code, there is a limitation on tax deductions of any publicly-held corporation for individual compensation to certain executives of such corporation exceeding \$1.0 million in any taxable year, unless the compensation is performance-based. The Compensation Committee manages our incentive programs to qualify for the performance-based exemption; however, it also reserves the right to provide compensation that does not meet the exemption criteria if, in its sole discretion, it determines that doing so advances our business objectives.

2016 Summary Compensation Table

The following table and narrative set forth certain information with respect to the compensation earned during the fiscal year ended December 31, 2016 by our named executive officers.

| Name and Principal Position | Year | Salary (\$) | Bonus (\$) | Stock Awards(1) (\$) | Option Awards(1) (\$) | All Other Compensation (\$) | Total(4) |
|--|-------------|------------------------|-------------------|-------------------------------------|--------------------------------------|--|-----------------|
| Gil Van Bokkelen, Chief Executive Officer(2) | 2016 | \$484,500 | \$154,071 | \$492,768 | \$695,000 | \$20,673 | \$1,847,012 |
| | 2015 | \$475,000 | \$122,550 | \$114,237 | \$188,707 | \$20,673 | \$921,167 |
| | 2014 | \$466,815 | \$133,000 | \$152,328 | \$286,598 | \$22,273 | \$1,061,014 |
| Laura Campbell, Senior Vice President of Finance | 2016 | \$270,000 | \$51,691 | \$148,464 | \$287,409 | \$13,509 | \$771,073 |
| | 2015 | \$251,750 | \$36,000 | \$57,119 | \$94,361 | \$13,509 | \$452,739 |
| | 2014 | \$247,265 | \$36,000 | \$76,164 | \$143,299 | \$13,109 | \$515,837 |
| William (BJ) Lehmann, Jr., President and Chief Operating Officer | 2016 | \$396,780 | \$96,417 | \$339,012 | \$502,068 | \$13,771 | \$1,348,048 |
| | 2015 | \$389,000 | \$80,000 | \$66,970 | \$110,619 | \$11,365 | \$657,954 |
| | 2014 | \$382,015 | \$82,500 | \$88,862 | \$167,190 | \$11,163 | \$731,730 |
| John Harrington, Chief Scientific Officer and Executive Vice President(2) | 2016 | \$394,740 | \$96,632 | \$327,168 | \$484,565 | \$10,723 | \$1,313,828 |
| | 2015 | \$387,000 | \$81,000 | \$66,970 | \$110,619 | \$10,723 | \$656,312 |
| | 2014 | \$380,015 | \$82,000 | \$88,862 | \$167,190 | \$10,523 | \$728,590 |

(1) Amounts do not reflect cash compensation actually received by our named executive officers. For example, the dollar amounts for annual stock awards represent a valuation of the award on the grant date, which vests over time, and does not represent cash proceeds. The fair value of restricted stock unit awards is calculated in accordance with Accounting Standards Codification 718, or ASC 718, excluding the impact of potential forfeitures. Assumptions used in the calculation of these amounts are included in the Notes to the audited consolidated financial statements included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2016.

(2) Drs. Van Bokkelen and Harrington also served as our Directors for 2016, 2015 and 2014 and did not receive any compensation as our Directors.

Grants of Plan-Based Awards for 2016

The following table sets forth plan-based equity awards granted to our named executive officers during 2016 under our equity compensation plans.

| Name | Grant Date | All Other Stock Awards: Number of Shares of Stock or Units (#) | All Other Option Awards: Number of Securities Underlying Options (#) | Exercise or Base Price of Option Awards (\$/sh) | Grant Date Fair Value of Stock and Option Awards \$(3) |
|---------------------------|------------------|---|---|---|--|
| Gil Van Bokkelen | June 20, 2016(1) | 225,008 | | | \$ 492,768 |
| | June 20, 2016(2) | | 500,000 | \$ 2.19 | \$ 695,000 |
| Laura Campbell | June 20, 2016(1) | 67,792 | | | \$ 148,464 |
| | March 7, 2016(2) | | 50,000 | \$ 1.84 | \$ 67,500 |
| | June 20, 2016(2) | | 158,208 | \$ 2.19 | \$ 219,909 |
| William (BJ) Lehmann, Jr. | June 20, 2016(1) | 154,800 | | | \$ 339,012 |
| | June 20, 2016(2) | | 361,200 | \$ 2.19 | \$ 502,068 |
| John Harrington | June 20, 2016(1) | 149,392 | | | \$ 327,168 |
| | June 20, 2016(2) | | 348,608 | \$ 2.19 | \$ 484,565 |

(1) Restricted stock units granted under our Long-Term Incentive Plan.

(2) Options granted under our Long-Term Incentive Plan.

(3) The amounts in this column represent the grant date fair value of the options calculated in accordance with ASC 718, excluding the impact of potential forfeitures.

Employment Agreements and Arrangements

Dr. Gil Van Bokkelen . On December 1, 1998, we entered into a one-year employment agreement, effective April 1, 1998, with Dr. Gil Van Bokkelen, to serve initially as President and Chief Executive Officer. The agreement automatically renews for subsequent one-year terms on April 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Dr. Van Bokkelen is entitled to a base salary and an annual discretionary incentive compensation payment of up to 33% of his base salary. His salary for 2017 is \$525,000 and his target annual incentive compensation payment is 60% of his base salary. Dr. Van Bokkelen also received options to purchase shares of common stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. Dr. Van Bokkelen is also entitled to life insurance coverage for the benefit of his family in the amount of at least \$1.0 million (which is \$2.0 million for 2017). For more information about severance arrangements under the agreement, see the disclosure under “Potential Payments Upon Termination or Change of Control.” Dr. Van Bokkelen has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of 18 months thereafter, he is restricted from, among other things, competing with us.

Dr. John J. Harrington . On December 1, 1998, we entered into a one-year employment agreement, effective April 1, 1998, with Dr. John J. Harrington to serve initially as Executive Vice President and Chief Scientific Officer. The agreement automatically renews for subsequent one-year terms on April 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Dr. Harrington is entitled to a base salary and an annual discretionary incentive compensation payment of up to 33% of his base salary. His salary for 2017 is \$406,750 and his target annual incentive compensation payment is 45% of his base salary. Dr. Harrington also received options to purchase shares of common stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. Dr. Harrington is also entitled to life insurance coverage for the benefit of his family in the amount of at least \$1.0 million (which is \$2.0 million for 2017). For more information about severance arrangements under the agreement, see the disclosure under “Potential Payments Upon Termination or Change of Control.” Dr. Harrington has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of 18 months thereafter, he is restricted from, among other things, competing with us.

William (B.J.) Lehmann, Jr. . On January 1, 2004, we entered into a four-year employment agreement with Mr. Lehmann to serve initially as Executive Vice President of Corporate Development and Finance. The agreement automatically renews for subsequent one-year terms on January 1 of each year unless either party gives notice of termination at least thirty days before the end of any term. The agreement was amended in 2013 to modify the duration of his severance arrangement, with no change to the events triggering such severance. Under the terms of the agreement, Mr. Lehmann is entitled to a base salary, which is \$409,000 for 2017. Mr. Lehmann's target annual incentive compensation payment for 2017 is 45% of his base salary. Mr. Lehmann also received options to purchase shares of common stock upon his employment that were terminated in 2007, and his current stock options are described in the table below. For more information about severance arrangements under the agreement, see the disclosure under "Potential Payments Upon Termination or Change of Control." Mr. Lehmann has also entered into a non-competition and confidentiality agreement with us under which, during his employment and for a period of twelve months thereafter, he is restricted from, among other things, competing with us.

Laura K. Campbell . On May 22, 1998, we entered into a two-year employment agreement with Laura K. Campbell to serve initially as Controller. The agreement automatically renews for subsequent one-year terms on May 22 of each year unless either party gives notice of termination at least thirty days before the end of any term. Under the terms of the agreement, Ms. Campbell is entitled to a base salary, which is \$278,500 for 2017. Ms. Campbell's target annual incentive compensation payment for 2017 is 35% of her base salary. Ms. Campbell also received options to purchase shares of common stock upon her employment that were terminated in 2007, and her current stock options are described in the table below. For more information about severance arrangements under the agreement, see the disclosure under "Potential Payments Upon Termination or Change of Control."

Equity Compensation Plans

In June 2007, we adopted two equity compensation plans, which authorize the Board of Directors, or a committee thereof, to provide equity-based compensation in the form of stock options, restricted stock, RSUs and other stock-based awards, which are used to attract and retain qualified employees, Directors and consultants. Equity awards are granted from time to time under the guidance and approval of the Compensation Committee. Total awards under these plans, as amended, are currently limited to 21,500,000 shares of Common Stock, of which 7,503,231 shares remain available for issuance at December 31, 2016.

401(k) Plan

We have a tax-qualified employee savings and retirement plan, also known as a 401(k) plan that covers all of our employees. Under our 401(k) plan, eligible employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit, which was \$18,000 in 2016, and have the amount of the reduced compensation contributed to the 401(k) plan. The trustees of the 401(k) plan, at the direction of each participant, invest the assets of the 401(k) plan in designated investment options. We may make matching or profit-sharing contributions to the 401(k) plan in amounts to be determined by the Board of Directors. We made matching contributions to the 401(k) plan during fiscal 2015 at a maximum rate of 100% of the first \$3,000 of participant contributions, plus 40% of participant contributions in excess of \$3,000 per participant, which amounted to approximately \$339,000 in 2016. The 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code, so that contributions to the 401(k) plan and income earned on the 401(k) plan contributions are not taxable until withdrawn, and so that any contributions we make will be deductible when made.

Outstanding Equity Awards at 2016 Fiscal Year-End

The following table sets forth outstanding equity awards held by our named executive officers at December 31, 2016.

| Name | Option Awards | | | | Stock Awards | |
|------------------|---|---|----------------------------|------------------------|---|--|
| | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price (\$) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested (\$) |
| Gil Van Bokkelen | 62,500 | 437,500 | \$ 2.19 | June 20, 2026(1) | — | — |
| | 75,282 | 125,470 | \$ 1.28 | June 24, 2025(1) | — | — |
| | 129,800 | 77,880 | \$ 1.65 | June 17, 2024(1) | — | — |
| | 161,875 | 23,125 | \$ 1.71 | June 18, 2023(1) | — | — |
| | 25,000 | 0 | \$ 5.28 | December 23, 2019(2) | — | — |
| | 712,500 | 0 | \$ 5.00 | June 8, 2017(3) | — | — |
| | — | — | — | — | 34,620(4) | \$ 52,969(5) |
| | — | — | — | — | 55,780(6) | \$ 85,343(5) |
| | — | — | — | — | 196,882(7) | \$ 301,229(5) |
| Laura Campbell | 19,776 | 138,432 | \$ 2.19 | June 20, 2026(1) | — | — |
| | 9,375 | 40,625 | \$ 1.84 | March 7, 2026(1) | — | — |
| | 37,644 | 62,740 | \$ 1.28 | June 24, 2025(1) | — | — |
| | 64,900 | 38,940 | \$ 1.65 | June 17, 2024(1) | — | — |
| | 52,500 | 7,500 | \$ 1.71 | June 18, 2023(1) | — | — |
| | 17,500 | 0 | \$ 5.28 | December 23, 2019(2) | — | — |
| | 200,000 | 0 | \$ 5.00 | June 8, 2017(3) | — | — |
| | — | — | — | — | 17,310(4) | \$ 26,484(5) |
| | — | — | — | — | 27,890(6) | \$ 42,672(5) |
| | — | — | — | — | 59,318(7) | \$ 90,757(5) |

| Name | Option Awards | | | | Stock Awards | |
|----------------------|---|---|----------------------------|------------------------|---|--|
| | Number of Securities Underlying Unexercised Options (#) | Number of Securities Underlying Unexercised Options (#) | Option Exercise Price (\$) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested (\$) |
| | Exercisable | Unexercisable | | | | |
| William (BJ) Lehmann | 45,150 | 316,050 | \$ 2.19 | June 20, 2026(1) | — | — |
| | 44,130 | 73,550 | \$ 1.28 | June 24, 2025(1) | — | — |
| | 75,720 | 45,432 | \$ 1.65 | June 17, 2024(1) | — | — |
| | 100,625 | 14,375 | \$ 1.71 | June 18, 2023(1) | — | — |
| | 22,500 | 0 | \$ 5.28 | December 23, 2019(2) | — | — |
| | 400,000 | 0 | \$ 5.00 | June 8, 2017(3) | — | — |
| | — | — | — | — | 20,196(4) | \$ 30,900(5) |
| | — | — | — | — | 32,700(6) | \$ 50,031(5) |
| | — | — | — | — | 135,450(7) | \$ 207,239(5) |
| John Harrington | 43,576 | 305,032 | \$ 2.19 | June 20, 2026(1) | — | — |
| | 44,130 | 73,550 | \$ 1.28 | June 24, 2025(1) | — | — |
| | 75,720 | 45,432 | \$ 1.65 | June 17, 2024(1) | — | — |
| | 87,500 | 12,500 | \$ 1.71 | June 18, 2023(1) | — | — |
| | 22,500 | 0 | \$ 5.28 | December 23, 2019(2) | — | — |
| | 700,000 | 0 | \$ 5.00 | June 8, 2017(3) | — | — |
| | — | — | — | — | 20,196(4) | \$ 30,900(5) |
| | — | — | — | — | 32,700(6) | \$ 50,031(5) |
| | — | — | — | — | 130,718(7) | \$ 199,999(5) |

- (1) Options vest ratably over four years on a quarterly basis.
- (2) Options were granted on December 23, 2009 and vested ratably over one year on a quarterly basis, and thus were fully exercisable on December 24, 2010.
- (3) Options were granted on June 8, 2007 and vested at a rate of 40% on the grant date and vested 20% in each of the three years thereafter (on a quarterly basis), and thus were fully exercisable on June 8, 2010.
- (4) The stock awards reflected in this column consist of RSUs granted on June 17, 2014, which vest over four years on a quarterly basis.
- (5) Value is based on the closing price of our common stock of \$1.53 on December 31, 2016, as reported on NASDAQ.
- (6) The stock awards reflected in this column consist of RSUs granted on June 24, 2015, which vest over four years on a quarterly basis.
- (7) The stock awards reflected in this column consist of RSUs granted on June 20, 2016, which vest over four years on a quarterly basis.

2016 Options Exercised and Stock Vested

The following table provides information on all stock awards vested and the value realized upon vesting, by the named executive officers during fiscal 2016. None of our named executive officers exercised any stock options during 2016.

| Name | Stock Awards | |
|----------------------|--|-----------------------------------|
| | Number of Shares Acquired on Vesting (#) | Value Realized on Vesting(1) (\$) |
| Gil Van Bokkelen | 189,358 | \$ 408,857 |
| Laura Campbell | 92,770 | \$ 202,926 |
| William (BJ) Lehmann | 141,500 | \$ 308,208 |
| John Harrington | 140,309 | \$ 305,823 |

- (1) The value realized upon vesting of these restricted stock units is the product of multiplying the number of shares of common stock issued upon vesting by the market value of the underlying shares on the vesting date. It does not represent cash proceeds to the employee until the underlying shares are sold.

Potential Payments Upon Termination or Change in Control

Under their employment agreements, the named executive officers may be entitled to certain potential payments upon termination. In the event that an executive officer is terminated without cause or terminates employment for good reason, as defined in the agreements, we would be obligated to pay full base salary for a defined period, subject to mitigation related to other employment. The defined payment period is eighteen months for Gil Van Bokkelen and John Harrington, twelve months for William (BJ) Lehmann and six months for Laura Campbell. We would also be obligated to continue the participation of Gil Van Bokkelen and John Harrington in all medical, life and employee “welfare” benefit programs for a period of eighteen months at our expense, to the extent available and possible under the programs.

The agreements define “cause” to mean willful and continuous neglect of such executive officer’s duties or responsibilities or willful misconduct by the executive officer that is materially and manifestly injurious to our Company. “Good reason” includes, among other things, demotion, salary reduction, relocation without consent, failure to provide an executive officer with adequate and appropriate facilities and termination by the executive officer within 90 days of a change in control. A “change in control” occurs when (1) a person or group of persons purchases 50% or more of our consolidated assets or a majority of our voting shares, or (2) if, following a public offering, the directors of Athersys immediately following the offering no longer constitute a majority of the Board of Directors. Upon a change in control, or if the named executive officer should die or become permanently disabled, all unvested stock options become immediately vested and exercisable. As of December 31, 2016, each of the named executive officers held unvested stock options and RSUs, as reflected in the Outstanding Equity Awards at 2016 Fiscal Year-End table above.

In the event that an executive officer is terminated for cause or as a result of death, we would be obligated to pay full base salary and other benefits, including any unpaid expense reimbursements, through the date of termination, and would have no further obligations to the executive officer. In the event that an executive officer is unable to perform duties as a result of a disability, we would be obligated to pay full base salary and other benefits until employment is terminated and for a period of twelve months from the date of such termination.

The table below reflects the amount of compensation payable to each named executive officer in the event of termination of such executive’s employment, pursuant to such executive’s employment agreement. The amounts shown assume that such termination was effective as of December 31, 2016 and thus includes amounts earned through such time and are estimates of the amounts that would be paid out to executives upon their termination.

| | Executive Benefit and Payments Upon Separation | Termination Without Cause or Voluntary For Good Reason |
|---------------------------|--|--|
| Gil Van Bokkelen | Cash Severance Payment | \$ 726,750 |
| | Continuation of Benefits | \$ 35,427 |
| | Total | \$ 762,177 |
| William (BJ) Lehmann, Jr. | Cash Severance Payment | \$ 396,780 |
| | Continuation of Benefits | \$ — |
| | Total | \$ 396,780 |
| John Harrington | Cash Severance Payment | \$ 592,110 |
| | Continuation of Benefits | \$ 35,427 |
| | Total | \$ 627,537 |
| Laura Campbell | Cash Severance Payment | \$ 135,000 |
| | Continuation of Benefits | \$ — |
| | Total | \$ 135,000 |

Director Compensation Table for 2016

The following table summarizes compensation paid to our non-employee Directors in 2016:

| Name(a) | Fees Earned or Paid in Cash (\$)(b) | Option Awards (\$)(1)(d) | Total (\$)(h) |
|----------------------|--|---------------------------------|----------------------|
| Lee E. Babiss | \$ 80,000 | \$ 127,500 | \$ 207,500 |
| Jordon S. Davis | \$ 25,185 | \$ 82,200 | \$ 107,385 |
| Ismail Kola | \$ 45,000 | \$ 127,500 | \$ 172,500 |
| Lorin J. Randall | \$ 70,000 | \$ 127,500 | \$ 197,500 |
| Kenneth H. Traub(2) | \$ 26,250 | \$ — | \$ 26,250 |
| Jack L. Wyszomierski | \$ 57,500 | \$ 127,500 | \$ 185,000 |

- (1) Amounts in column (d) do not necessarily reflect compensation actually received by our Directors. The amounts in column (d) reflect the full grant date fair value of the equity awards made during the fiscal year ended December 31, 2016, in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in the notes to the 2016 audited consolidated financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2016. Lee Babiss, Ismail Kola, Lorin Randall and Jack Wyszomierski each had 225,000 option awards outstanding as of December 31, 2016. Jordon Davis had 60,000 option awards outstanding as of December 31, 2016.
- (2) Mr. Traub retired as a Director at our 2016 annual meeting of stockholders in June 2016.

Under our Director compensation program for non-employee Directors, new Directors receive an initial stock option grant to purchase 50,000 shares of common stock at fair market value on the date of grant, which vests at a rate of 50% in the first year (on a quarterly basis) and 25% in each of the two years (on a quarterly basis) thereafter. In March 2016, the Directors approved a change to the compensation program, whereby the initial stock option grant would be increased from 50,000 to 60,000 shares of common stock, and would vest at a rate of 33.33% per year, with cliff vesting in year one and quarterly vesting in years two and three. Also, given that awards from their initial appointment over five years ago had expired, Directors Babiss, Kola, Randall and Wyszomierski each received stock option awards in March 2016 to purchase 75,000 shares of common stock.

Additionally, the non-employee Directors receive annually an option award to purchase 30,000 shares of our common stock at fair market value on the date of grant, which vests quarterly over a one-year period, with such anniversary awards issued in June of each year in connection with our annual stockholder meeting. In June 2016, Directors Babiss, Kola, Randall, and Wyszomierski each received an anniversary stock option award of 30,000 shares. All initial and anniversary stock option awards granted to non-employee Directors have a term of ten years and upon the termination of the Director's service, the Director has eighteen months in which to exercise the vested portion of his options prior to forfeiture.

Our Directors receive annual cash compensation retainers as set forth below:

| | |
|---|-----------|
| Board Member | \$ 40,000 |
| Lead Director | \$ 25,000 |
| Audit Committee — Chairman | \$ 15,000 |
| Audit Committee — Member | \$ 7,500 |
| Compensation Committee — Chairman | \$ 10,000 |
| Compensation Committee — Member | \$ 5,000 |
| Nominations and Corporate Governance Committee — Chairman | \$ 10,000 |
| Nominations and Corporate Governance Committee — Member | \$ 5,000 |

These annual retainers are paid in quarterly installments and Directors are reimbursed for reasonable out-of-pocket expenses incurred while attending Board and committee meetings. In January 2017, the retainers were increased as follows: Audit Committee Chairman, \$20,000; Audit Committee Member \$9,000; Compensation Committee Chairman, \$13,000; and Compensation Committee Member \$6,000.

Compensation Committee Interlocks and Insider Participation

In 2016, none of our Directors was a member of the board of directors of any other company where the relationship would be construed to constitute a committee interlock within the meaning of the rules of the SEC.

COMPENSATION COMMITTEE REPORT

The Compensation Committee has reviewed and discussed with management the Compensation Discussion and Analysis section above and based on this review, has recommended to the Board of Directors the inclusion of the Compensation Discussion and Analysis in this annual report on Form 10-K for the fiscal year ended December 31, 2016.

Compensation Committee
Board of Directors

Lee E. Babiss
Lorin J. Randall
Jack W. Wyszomierski

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth certain information regarding the Company's equity compensation plans as of December 31, 2016, unless otherwise indicated.

| <u>Plan Category</u> | Number of securities to be issued upon exercise of outstanding awards <u>(a)(1)</u> | Weighted-average exercise price of outstanding awards <u>(b)(2)</u> | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) <u>(c)(1)</u> |
|--|--|--|--|
| Equity compensation plan approved by security holders | 9,288,151 | \$ 2.79 | 7,298,217 |
| Equity compensation plan not approved by security holders(3) | 1,149,236 | \$ 2.57 | 205,014 |
| Total | 10,437,387 | | 7,503,231 |

- (1) Included in column (a) and (c) are both stock option and RSU awards under our equity compensation plans.
- (2) Reflects the weighted-average exercise price of outstanding options only, as opposed to RSUs that do not have an exercise price. The weighted average exercise price of all outstanding awards under plans is \$2.76 and the weighted average remaining term is 5.78 years.
- (3) The other shares of common stock included in this plan category are issued or issuable under our Equity Incentive Compensation Plan. The terms of our Equity Incentive Compensation Plan are substantially similar to the terms of our primary incentive plan. For information on the terms of these plans, see "Compensation Discussion and Analysis – Elements of Executive Compensation – Long-Term Incentive Program", as well as "Compensation Discussion and Analysis – Equity Compensation Plans".

BENEFICIAL OWNERSHIP OF COMMON STOCK

The following table sets forth certain information known to us regarding the beneficial ownership of our common stock as of February 28, 2017 (unless otherwise indicated below) by:

- each person known by us to beneficially own more than 5% of our common stock;
- each of our Directors and nominees;
- each of the executive officers named in the Summary Compensation Table; and
- all of our Directors and nominees and executive officers as a group.

We determined beneficial ownership in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock that could be issued upon the exercise of outstanding options, RSUs and warrants held by that person that are exercisable within 60 days of February 28, 2017 are considered outstanding. These shares, however, are not considered outstanding when computing the percentage ownership of each other person.

Percentage ownership calculations for beneficial ownership for each person or entity are based on 109,562,375 shares of common stock outstanding as of February 28, 2017.

Except as indicated in the footnotes to this table and pursuant to state community property laws, each stockholder named in the table has sole voting and investment power for the shares shown as beneficially owned by them.

| Name of Beneficial Owner | Number of Shares | Percent of Class |
|---|---------------------|---------------------|
| Greater Than 5% Stockholders | | |
| None | — | — |
| Directors, Nominees and Executive Officers | | |
| Gil Van Bokkelen(1) | 2,024,905 | 1.9% |
| Lee Babiss(2) | 173,750 | * |
| John Harrington(3) | 1,435,395 | 1.3% |
| Ismail Kola(2) | 188,750 | * |
| Lorin Randall(2) | 173,750 | * |
| Jack Wyszomierski(2) | 173,750 | * |
| Jordan Davis(4) | 4,292,788 | 3.9% |
| Laura Campbell(5) | 838,430 | * |
| William (BJ) Lehmann, Jr.(6) | 952,881 | * |
| All Directors, Nominees and executive officers as a group (9 persons) | 10,254,399 | 9.4% |

* Less than 1%.

- (1) Includes vested options for 1,235,296 shares of common stock at a weighted average exercise price of \$3.68 per share and 25,411 RSUs that vest within 60 days of February 28, 2017.
- (2) Includes vested options for 173,750 shares of common stock at a weighted average exercise price of \$1.77 per share.
- (3) Includes vested options for 1,016,391 shares of common stock at a weighted average exercise price of \$4.06 per share and 15,973 RSUs that vest within 60 days of February 28, 2017.
- (4) Includes 4,248,788 shares of common stock held by Radius and its affiliates, over which Mr. Davis has shared voting and dispositive power, and 4,000 shares of common stock held by Mr. Davis' children, over which Mr. Davis has shared voting and dispositive power. The address for Radius and its affiliates is 250 Park Avenue, Suite 1102 New York, New York 10177.
- (5) Includes vested options for 431,222 shares of common stock at a weighted average exercise price of \$3.36 per share and 9,911 RSUs that vest within 60 days of February 28, 2017.
- (6) Includes vested options for 732,815 shares of common stock at a weighted average exercise price of \$3.62 per share and 16,311 RSUs that vest within 60 days of February 28, 2017.

Section 16(a) Beneficial Ownership Reporting Compliance

Based solely on a review of reports of ownership, reports of changes of ownership and written representations under Section 16(a) of the Exchange Act that were furnished to the Company during or with respect to fiscal year 2016 by persons who were, at any time during fiscal year 2016, Directors or officers of the Company or beneficial owners of more than 10% of the outstanding shares of common stock, all filing requirements for reporting persons were met.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Certain Relationships and Related Person Transactions

We give careful attention to related person transactions because they may present the potential for conflicts of interest. We refer to “related person transactions” as those transactions, arrangements, or relationships in which:

- we were, are or are to be a participant;
- the amount involved exceeds \$120,000; and
- any of our Directors, Director nominees, executive officers or greater-than five percent stockholders (or any of their immediate family members) had or will have a direct or indirect material interest.

To identify related person transactions in advance, we rely on information supplied by our executive officers, Directors and certain significant stockholders. We maintain a comprehensive written policy for the review, approval or ratification of related person transactions, and our Audit Committee reviews all related person transactions identified by us. The Audit Committee approves or ratifies only those related person transactions that are determined by it to be, under all of the circumstances, in the best interest of the Company and its stockholders. No related person transactions occurred in fiscal 2016 that required a review by the Audit Committee.

Director Independence

The Board reviews the independence of each Director at least annually. During these reviews, the Board will consider transactions and relationships between each Director (and his or her immediate family and affiliates) and the Company and our management to determine whether any such transactions or relationships are inconsistent with a determination that the Director was independent. The Board conducted its annual review of Director independence to determine if any transactions or relationships exist that would disqualify any of the individuals who serve as a Director under the rules of the NASDAQ Capital Market or require disclosure under Securities and Exchange Commission, or SEC, rules. Based upon the foregoing review, the Board determined the following individuals are independent under the rules of the NASDAQ Capital Market: Lee E. Babiss, Jordan S. Davis, Ismail Kola, Lorin J. Randall, and Jack L. Wyszomierski. Currently, we have two members of management that also serve on the Board: Dr. Van Bokkelen, who is also our Chairman and Chief Executive Officer, and Dr. Harrington, who is our Executive Vice President and Chief Scientific Officer. Neither Dr. Van Bokkelen nor Dr. Harrington is considered independent under the independence rules of the NASDAQ Capital Market.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Principal Accountant Fees and Services

Audit Fees . Fees paid to Ernst & Young LLP for the audit of the annual consolidated financial statements included in the Company’s Annual Reports on Form 10-K, for the reviews of the consolidated financial statements included in the Company’s Forms 10-Q, and for services related to registration statements were \$489,100 for the fiscal year ended December 31, 2016 and \$522,800 for the fiscal year ended December 31, 2015. The decrease related primarily to services for registration statements filed in 2015.

Audit-Related Fees . Fees paid to Ernst & Young LLP for audit-related services in 2016 and 2015 were \$29,500 and \$35,000, respectively, related to grant-required attestation.

Tax Fees . Fees paid to Ernst & Young LLP associated with tax compliance and tax consultation were \$35,000 and \$62,223 for the fiscal years ended December 31, 2016 and 2015, respectively. The decrease related primarily to services related to international tax consultations and a change in method.

All Other Fees . There were no other fees paid to Ernst & Young LLP in 2016 or 2015.

Audit Committee Pre-Approval Policies and Procedures

The Audit Committee has adopted a formal policy on auditor independence requiring the pre-approval by the Audit Committee of all professional services rendered by the Company's independent auditor prior to the commencement of the specified services.

For the fiscal year ended December 31, 2016 and 2015, 100% of the services described above were pre-approved by the Audit Committee in accordance with the Company's formal policy on auditor independence.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements:

The following consolidated financial statements of Athersys, Inc. are included in Item 8:

- Reports of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of December 31, 2016 and 2015
- Consolidated Statements of Operations and Comprehensive Loss for each of the years ended December 31, 2016, 2015 and 2014
- Consolidated Statements of Stockholders' Equity for each of the years ended December 31, 2016, 2015 and 2014
- Consolidated Statements of Cash Flow for each of the years ended December 31, 2016, 2015 and 2014
- Notes to Consolidated Financial Statements

(a)(2) Financial Statement Schedules:

The following financial statement schedule of Athersys, Inc. is included:

Schedule II – Valuation and Qualifying Accounts

| (In thousands) | Balance at Beginning of Year | Additions | Deductions | Balance at End of Year |
|--|------------------------------------|------------------|-------------|---------------------------|
| Year Ended December 31, 2016 | | | | |
| Deducted from asset accounts: | | | | |
| Allowance for doubtful accounts- note receivable | \$ 363 | \$ 13 | \$ — | \$ 376(A) |
| Tax valuation allowances | \$ 48,921 | \$ 5,851 | \$ — | \$ 54,772 |
| Total 2016 | \$ 49,284 | \$ 5,864 | \$ — | \$ 55,148 |
| Year Ended December 31, 2015 | | | | |
| Deducted from asset accounts: | | | | |
| Allowance for doubtful accounts- note receivable | \$ 352 | \$ 11 | \$ — | \$ 363(A) |
| Tax valuation allowances | \$ 41,852 | \$ 7,069 | \$ — | \$ 48,921 |
| Total 2015 | \$ 42,204 | \$ 7,080 | \$ — | \$ 49,284 |
| Year Ended December 31, 2014 | | | | |
| Deducted from asset accounts: | | | | |
| Allowance for doubtful accounts- note receivable | \$ 341 | \$ 11 | \$ — | \$ 352(A) |
| Tax valuation allowances | \$ 26,042 | \$ 15,810 | \$ — | \$ 41,852 |
| Total 2014 | \$ 26,383 | \$ 15,812 | \$ — | \$ 42,204 |

(A) – Reserve on note receivable; fully-reserved.

(B) – Substantially all of our deferred tax assets are offset by valuation allowances.

[Table of Contents](#)

All other schedules for which provision is made in the applicable accounting regulation of the SEC are not required under the related instructions or are inapplicable and, therefore, omitted.

(a)(3) Exhibits.

| Exhibit No. | Exhibit Description |
|-------------|--|
| 3.1 | Certificate of Incorporation of Athersys, Inc., as amended as of June 28, 2013 (incorporated herein by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on August 13, 2013) |
| 3.2 | Bylaws of Athersys, Inc., as amended as of October 30, 2007 (incorporated herein by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on October 31, 2007) |
| 4.1 | Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on March 15, 2012) |
| 4.5 | Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on January 13, 2014) |
| 10.1* | Research Collaboration and License Agreement, dated as of December 8, 2000, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.2* | Cell Line Collaboration and License Agreement, dated as of July 1, 2002, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on September 27, 2007) |
| 10.3 | Amendment No. 1 to Cell Line Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.36 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.4* | Extended Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on September 27, 2007) |
| 10.5 | Amendment dated as of March 31, 2009 to the Extended Collaboration and License Agreement, by and between Athersys, Inc. and Bristol-Myers Squibb Company effective January 1, 2006 (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on April 9, 2009) |
| 10.6 | Amendment No. 3 to Extended Collaboration and License Agreement, dated January 31, 2012, by and between ABT Holding Company and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on May 14, 2012) |

[Table of Contents](#)

- 10.7 Amended and Restated Registration Rights Agreement, dated as of April 28, 2000, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto (incorporated herein by reference to Exhibit 10.6 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.8 Amendment No. 1 to Athersys, Inc. Amended and Restated Registration Rights Agreement, dated as of January 29, 2002, by and among Athersys, Inc., the New Stockholders, the Investors, Biotech and the Stockholders (each as defined in the Amended and Restated Registration Rights Agreement, dated as April 28, 2000, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.7 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.9 Amendment No. 2 to Athersys, Inc. Amended and Restated Registration Rights Agreement, dated as of November 19, 2002, by and among Athersys, Inc., the New Stockholders, the Investors, Biotech and the Stockholders (each as defined in the Amended and Restated Registration Rights Agreement, dated as April 28, 2000, as amended, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.8 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.10 Amendment No. 3 to Amended and Restated Registration Rights Agreement, dated as of May 15, 2007, by and among Athersys, Inc. and the Existing Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.9 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.11 Amendment No. 4 to Amended and Restated Registration Rights Agreement, dated as of March 8, 2010, by and among Athersys, Inc. and the Existing Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.45 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (Commission No. 001-33876) filed with the Commission on March 11, 2010)
- 10.12† Athersys, Inc. Equity Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.11 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.13† Amended and Restated Employment Agreement, dated as of December 1, 1998 but effective as of April 1, 1998, by and between Athersys, Inc. and Dr. Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.14 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.14† Amendment No. 1 to Amended and Restated Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.15 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.15† Non-Competition and Confidentiality Agreement, dated as of December 1, 1998, by and between Athersys, Inc. and Dr. Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.16 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.16† Amended and Restated Employment Agreement, dated as of December 1, 1998 but effective as of April 1, 1998, by and between Athersys, Inc. and Dr. John J. Harrington (incorporated herein by reference to Exhibit 10.17 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.17† Amendment No. 1 to Amended and Restated Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and John Harrington (incorporated herein by reference to Exhibit 10.18 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.18† Non-Competition and Confidentiality Agreement, dated as of December 1, 1998, by and between Athersys, Inc. and Dr. John J. Harrington (incorporated herein by reference to Exhibit 10.19 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.19† Employment Agreement, dated as of May 22, 1998, by and between Athersys, Inc. and Laura K. Campbell (incorporated herein by reference to Exhibit 10.20 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.20† Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Laura Campbell (incorporated herein by reference to Exhibit 10.21 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.21† Employment Agreement, dated as of January 1, 2004, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.28 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)

[Table of Contents](#)

| | |
|---------|--|
| 10.22† | Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.29 to the registrant’s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 110.23† | Amendment No. 2 to Employment Agreement, dated as of January 24, 2014, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.24 to the registrant’s Annual Report on Form 10-K for the year ended December 31, 2013 (Commission No. 001-33876) filed with the Commission on March 13, 2014) |
| 10.24† | Non-Competition and Confidentiality Agreement, dated as of September 10, 2001, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.30 to the registrant’s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.25† | Consulting Agreement, dated as of September 1, 2015, by and between Advanced Biotherapeutics, Inc. and Robert Deans (incorporated herein by reference to Exhibit 10.1 to the registrant’s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on November 5, 2015) |
| 10.26† | Form Incentive Agreement by and between Advanced Biotherapeutics, Inc. and named executive officers, and acknowledged by Athersys, Inc. and ReGenesys, LLC (incorporated herein by reference to Exhibit 10.31 to the registrant’s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.27† | Form Amendment No. 1 to Incentive Agreement by and between Advanced Biotherapeutics, Inc. and named executive officers, and acknowledged by Athersys, Inc. and ReGenesys, LLC (incorporated herein by reference to Exhibit 10.32 to the registrant’s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.28† | Form Amendment No. 2 to Incentive Agreement by and between Advanced Biotherapeutics, Inc. and named executive officers, and acknowledged by Athersys, Inc. and ReGenesys, LLC (incorporated herein by reference to Exhibit 10.2 to the registrant’s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 20, 2013) |
| 10.29* | Exclusive License Agreement, dated as of May 17, 2002, by and between Regents of the University of Minnesota and MCL LLC, assumed by ReGenesys, LLC through operation of merger on November 4, 2003 (incorporated herein by reference to Exhibit 10.34 to the registrant’s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.30 | Form Indemnification Agreement for Directors, Officers and Directors and Officers (incorporated herein by reference to Exhibit 10.1 to the registrant’s Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on August 6, 2007) |
| 10.31* | License and Technical Assistance Agreement, dated as of September 10, 2010, between ABT Holding Company and RTI (incorporated herein by reference to Exhibit 10.1 to the registrant’s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on November 8, 2010) |
| 10.32† | Form of Incentive Stock Option Agreement (incorporated herein by reference to Exhibit 10.47 to the registrant’s Annual Report on Form 10-K for the year ended December 31, 2010 (Commission No. 001-33876) filed with the Commission on March 25, 2011) |
| 10.33† | Form of Nonqualified Stock Option Agreement for Non-Employee Directors (incorporated herein by reference to Exhibit 10.48 to the registrant’s Annual Report on Form 10-K for the year ended December 31, 2010 (Commission No. 001-33876) filed with the Commission on March 25, 2011) |

[Table of Contents](#)

| | |
|---------|---|
| 10.34† | Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 4.1 to the Company’s Registration Statement on Form S-8 (Registration No. 333-212119) filed with the Securities and Exchange Commission on June 20, 2016) |
| 10.35† | Form of Nonqualified Stock Option Agreement for Non-Employee Directors pursuant to the Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (Amended and Restated Effective June 16, 2011) (incorporated herein by reference to Exhibit 10.49 to the registrant’s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on May 6, 2011) |
| 10.36† | Form of Restricted Stock Unit Agreement (incorporated herein by reference to Exhibit 10.2 to the registrant’s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on August 10, 2011) |
| 10.37† | Form of Restricted Stock Unit Agreement (incorporated herein by reference to Exhibit 10.2 to the registrant’s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on June 20, 2013) |
| 10.38 | First Amendment to License and Technical Assistance Agreement, dated September 17, 2012, by and between ABT Holding, Inc. and RTI Biologics, Inc. (incorporated herein by reference to Exhibit 10.52 to the registrant’s Registration Statement on Form S-1/A (Registration No. 001-33876) |
| 10.39† | Summary of Athersys, Inc. 2016 Cash Bonus Incentive Plan (incorporated herein by reference to Exhibit 10.50 to the registrant’s Annual Report on Form 10-K for the year ended December 31, 2015 (Commission No. 001-33876) filed with the Commission on March 12, 2016) |
| 10.40 | Common Stock Purchase Agreement, dated as of December 17, 2015, by and between Athersys, Inc. and Aspire Capital Fund LLC (incorporated herein by reference to Exhibit 10.2 to the registrant’s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on December 17, 2015) |
| 10.41 | Registration Rights Agreement, dated as of December 17, 2015, by and between Athersys, Inc. and Aspire Capital Fund LLC (incorporated herein by reference to Exhibit 10.2 to the registrant’s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on December 17, 2015) |
| 10.42† | Summary of Athersys, Inc. 2017 Cash Bonus Incentive Plan |
| 10.43 | License Agreement by and between ABT Holding Company and Healios K.K., dated as of January 8, 2016 (incorporated herein by reference to Exhibit 10.1 to the registrant’s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on May 5, 2016) |
| 21.1 | List of Subsidiaries |
| 23.1 | Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm |
| 24.1 | Power of Attorney |
| 31.1 | Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Laura K. Campbell, Senior Vice President of Finance, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, and Laura Campbell, Senior Vice President of Finance, pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

* Confidential treatment requested as to certain portions, which portions have been filed separately with the SEC

† Indicates management contract or compensatory plan, contract or arrangement in which one or more directors or executive officers of the registrant may be participants

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 to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Cleveland, State of Ohio, on March 10, 2017.

ATHERSYS, INC.

By: /s/ Gil Van Bokkelen
Gil Van Bokkelen
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|---|----------------|
| <u>/s/ Gil Van Bokkelen</u> Gil Van Bokkelen | Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer) | March 10, 2017 |
| <u>/s/ Laura K. Campbell</u> Laura K. Campbell | Senior Vice President of Finance (Principal Financial Officer and Principal Accounting Officer) | March 10, 2017 |
| <u>*</u> John J. Harrington | Executive Vice President, Chief Scientific Officer and Director | March 10, 2017 |
| <u>*</u> Lorin J. Randall | Director | March 10, 2017 |
| <u>*</u> Kenneth H. Traub | Director | March 10, 2017 |
| <u>*</u> Jack L. Wyszomierski | Director | March 10, 2017 |
| <u>*</u> Lee E. Babiss | Director | March 10, 2017 |
| <u>*</u> Ismail Kola | Director | March 10, 2017 |

* Gil Van Bokkelen, by signing his name hereto, does hereby sign this Form 10-K on behalf of each of the above named and designated directors of the Company pursuant to Powers of Attorney executed by such persons and filed with the Securities and Exchange Commission.

By: /s/ Gil Van Bokkelen
Gil Van Bokkelen
Attorney-in-fact

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Exhibit Description</u> |
|--------------------|--|
| 3.1 | Certificate of Incorporation of Athersys, Inc., as amended as of June 28, 2013 (incorporated herein by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q (Commission No. 000-52108) filed with the Commission on August 13, 2013) |
| 3.2 | Bylaws of Athersys, Inc., as amended as of October 30, 2007 (incorporated herein by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on October 31, 2007) |
| 4.1 | Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on March 15, 2012) |
| 4.5 | Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on January 13, 2014) |
| 10.1* | Research Collaboration and License Agreement, dated as of December 8, 2000, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.2* | Cell Line Collaboration and License Agreement, dated as of July 1, 2002, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on September 27, 2007) |
| 10.3 | Amendment No. 1 to Cell Line Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.36 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.4* | Extended Collaboration and License Agreement, dated as of January 1, 2006, by and between Athersys, Inc. and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K/A (Commission No. 000-52108) filed with the Commission on September 27, 2007) |
| 10.5 | Amendment dated as of March 31, 2009 to the Extended Collaboration and License Agreement, by and between Athersys, Inc. and Bristol-Myers Squibb Company effective January 1, 2006 (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on April 9, 2009) |
| 10.6 | Amendment No. 3 to Extended Collaboration and License Agreement, dated January 31, 2012, by and between ABT Holding Company and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on May 14, 2012) |

[Table of Contents](#)

- 10.7 Amended and Restated Registration Rights Agreement, dated as of April 28, 2000, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto (incorporated herein by reference to Exhibit 10.6 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.8 Amendment No. 1 to Athersys, Inc. Amended and Restated Registration Rights Agreement, dated as of January 29, 2002, by and among Athersys, Inc., the New Stockholders, the Investors, Biotech and the Stockholders (each as defined in the Amended and Restated Registration Rights Agreement, dated as April 28, 2000, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.7 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.9 Amendment No. 2 to Athersys, Inc. Amended and Restated Registration Rights Agreement, dated as of November 19, 2002, by and among Athersys, Inc., the New Stockholders, the Investors, Biotech and the Stockholders (each as defined in the Amended and Restated Registration Rights Agreement, dated as April 28, 2000, as amended, by and among Athersys, Inc. and the stockholders of Athersys, Inc. parties thereto) (incorporated herein by reference to Exhibit 10.8 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.10 Amendment No. 3 to Amended and Restated Registration Rights Agreement, dated as of May 15, 2007, by and among Athersys, Inc. and the Existing Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.9 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.11 Amendment No. 4 to Amended and Restated Registration Rights Agreement, dated as of March 8, 2010, by and among Athersys, Inc. and the Existing Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.45 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (Commission No. 001-33876) filed with the Commission on March 11, 2010)
- 10.12† Athersys, Inc. Equity Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.11 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.13† Amended and Restated Employment Agreement, dated as of December 1, 1998 but effective as of April 1, 1998, by and between Athersys, Inc. and Dr. Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.14 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.14† Amendment No. 1 to Amended and Restated Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.15 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.15† Non-Competition and Confidentiality Agreement, dated as of December 1, 1998, by and between Athersys, Inc. and Dr. Gil Van Bokkelen (incorporated herein by reference to Exhibit 10.16 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.16† Amended and Restated Employment Agreement, dated as of December 1, 1998 but effective as of April 1, 1998, by and between Athersys, Inc. and Dr. John J. Harrington (incorporated herein by reference to Exhibit 10.17 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.17† Amendment No. 1 to Amended and Restated Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and John Harrington (incorporated herein by reference to Exhibit 10.18 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.18† Non-Competition and Confidentiality Agreement, dated as of December 1, 1998, by and between Athersys, Inc. and Dr. John J. Harrington (incorporated herein by reference to Exhibit 10.19 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.19† Employment Agreement, dated as of May 22, 1998, by and between Athersys, Inc. and Laura K. Campbell (incorporated herein by reference to Exhibit 10.20 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.20† Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and Laura Campbell (incorporated herein by reference to Exhibit 10.21 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)
- 10.21† Employment Agreement, dated as of January 1, 2004, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.28 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007)

[Table of Contents](#)

| | |
|---------|--|
| 10.22† | Amendment No. 1 to Employment Agreement, dated as of May 31, 2007, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.29 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 110.23† | Amendment No. 2 to Employment Agreement, dated as of January 24, 2014, by and between Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.24 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2013 (Commission No. 001-33876) filed with the Commission on March 13, 2014) |
| 10.24† | Non-Competition and Confidentiality Agreement, dated as of September 10, 2001, by and among Athersys, Inc., Advanced Biotherapeutics, Inc. and William Lehmann (incorporated herein by reference to Exhibit 10.30 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.25† | Consulting Agreement, dated as of September 1, 2015, by and between Advanced Biotherapeutics, Inc. and Robert Deans (incorporated herein by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on November 5, 2015) |
| 10.26† | Form Incentive Agreement by and between Advanced Biotherapeutics, Inc. and named executive officers, and acknowledged by Athersys, Inc. and ReGenesys, LLC (incorporated herein by reference to Exhibit 10.31 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.27† | Form Amendment No. 1 to Incentive Agreement by and between Advanced Biotherapeutics, Inc. and named executive officers, and acknowledged by Athersys, Inc. and ReGenesys, LLC (incorporated herein by reference to Exhibit 10.32 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.28† | Form Amendment No. 2 to Incentive Agreement by and between Advanced Biotherapeutics, Inc. and named executive officers, and acknowledged by Athersys, Inc. and ReGenesys, LLC (incorporated herein by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 20, 2013) |
| 10.29* | Exclusive License Agreement, dated as of May 17, 2002, by and between Regents of the University of Minnesota and MCL LLC, assumed by ReGenesys, LLC through operation of merger on November 4, 2003 (incorporated herein by reference to Exhibit 10.34 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on June 14, 2007) |
| 10.30 | Form Indemnification Agreement for Directors, Officers and Directors and Officers (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 000-52108) filed with the Commission on August 6, 2007) |
| 10.31* | License and Technical Assistance Agreement, dated as of September 10, 2010, between ABT Holding Company and RTI (incorporated herein by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on November 8, 2010) |
| 10.32† | Form of Incentive Stock Option Agreement (incorporated herein by reference to Exhibit 10.47 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2010 (Commission No. 001-33876) filed with the Commission on March 25, 2011) |
| 10.33† | Form of Nonqualified Stock Option Agreement for Non-Employee Directors (incorporated herein by reference to Exhibit 10.48 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2010 (Commission No. 001-33876) filed with the Commission on March 25, 2011) |

[Table of Contents](#)

| | |
|---------|---|
| 10.34† | Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 4.1 to the Company’s Registration Statement on Form S-8 (Registration No. 333-212119) filed with the Securities and Exchange Commission on June 20, 2016) |
| 10.35† | Form of Nonqualified Stock Option Agreement for Non-Employee Directors pursuant to the Athersys, Inc. Amended and Restated 2007 Long-Term Incentive Plan (Amended and Restated Effective June 16, 2011) (incorporated herein by reference to Exhibit 10.49 to the registrant’s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on May 6, 2011) |
| 10.36† | Form of Restricted Stock Unit Agreement (incorporated herein by reference to Exhibit 10.2 to the registrant’s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on August 10, 2011) |
| 10.37† | Form of Restricted Stock Unit Agreement (incorporated herein by reference to Exhibit 10.2 to the registrant’s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on June 20, 2013) |
| 10.38 | First Amendment to License and Technical Assistance Agreement, dated September 17, 2012, by and between ABT Holding, Inc. and RTI Biologics, Inc. (incorporated herein by reference to Exhibit 10.52 to the registrant’s Registration Statement on Form S-1/A (Registration No. 001-33876) |
| 10.39† | Summary of Athersys, Inc. 2015 Cash Bonus Incentive Plan (incorporated herein by reference to Exhibit 10.50 to the registrant’s Annual Report on Form 10-K for the year ended December 31, 2014 (Commission No. 001-33876) filed with the Commission on March 12, 2016) |
| 10.40 | Common Stock Purchase Agreement, dated as of December 17, 2015, by and between Athersys, Inc. and Aspire Capital Fund LLC (incorporated herein by reference to Exhibit 10.2 to the registrant’s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on December 17, 2015) |
| 10.41 | Registration Rights Agreement, dated as of December 17, 2015, by and between Athersys, Inc. and Aspire Capital Fund LLC (incorporated herein by reference to Exhibit 10.2 to the registrant’s Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on December 17, 2015) |
| 10.42† | Summary of Athersys, Inc. 2017 Cash Bonus Incentive Plan |
| 10.43 | License Agreement by and between ABT Holding Company and Healios K.K., dated as of January 8, 2016 (incorporated herein by reference to Exhibit 10.1 to the registrant’s Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on May 5, 2016) |
| 21.1 | List of Subsidiaries |
| 23.1 | Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm |
| 24.1 | Power of Attorney |
| 31.1 | Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Laura K. Campbell, Senior Vice President of Finance, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Gil Van Bokkelen, Chairman and Chief Executive Officer, and Laura Campbell, Senior Vice President of Finance, pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

* Confidential treatment requested as to certain portions, which portions have been filed separately with the SEC

† Indicates management contract or compensatory plan, contract or arrangement in which one or more directors or executive officers of the registrant may be participants

SUMMARY OF ATHERSYS, INC.
2017 CASH BONUS INCENTIVE PLAN

On January 11, 2017, the Board of Directors of Athersys, Inc. (the “Company”), based upon the recommendation of the Compensation Committee of the Board of Directors of the Company, approved a cash bonus incentive plan (the “Plan”) for the year ended December 31, 2017 for the named executive officers of the Company. The Plan provides that each participant is eligible to earn a bonus during the award term of January 1, 2017 through December 31, 2017. The Plan provides for the following target bonus percentages of the named executive officer’s salary during the award term, weighted as set forth below on the achievement of specified corporate goals, with the remainder based on individual/functional performance. The corporate goals include advancing the Company’s clinical programs for MultiStem, executing against the established operating plan and capital acquisition objectives, and advancement of strategic partnership and program activities. There is no formally adopted plan document for the Plan.

| <u>Title</u> | <u>Target Bonus</u> | <u>Weighting on Corporate Goals</u> |
|---|---------------------|-------------------------------------|
| Chief Executive Officer | 60% | 100% |
| President & Chief Operating Officer | 45% | 80% |
| Executive Vice President & Chief Scientific Officer | 45% | 80% |
| Senior Vice President of Finance | 35% | 60% |

SUBSIDIARIES OF ATHERSYS, INC.

| <u>Name of Subsidiary</u> | <u>Jurisdiction</u> |
|---|----------------------------|
| ABT Holding Company (formerly Athersys, Inc.) | Delaware |
| Advanced Biotherapeutics, Inc. | Delaware |
| Athersys Limited | United Kingdom |
| ReGenesys LLC | Delaware |
| ReGenesys BVBA | Belgium |
| ReGenesys EU NV | Belgium |

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3MEF, No. 333-215772) dated January 27, 2017,
- (2) Registration Statement (Form S-8, No. 333-212119) dated June 20, 2016 pertaining to the Amended and Restated 2007 Long-Term Incentive Plan,
- (3) Registration Statement (Form S-3, No. 333-208629) dated January 13, 2016,
- (4) Registration Statement (Form S-8, No. 333-189406) dated June 18, 2013 pertaining to the Athersys, Inc. Long-Term Incentive Plan,
- (5) Registration Statement (Form S-8, No. 333-175023) dated June 20, 2011 pertaining to the Athersys, Inc. Long-Term Incentive Plan,
- (6) Registration Statement (Form S-8, No. 333-147379) dated November 14, 2007 pertaining to the Athersys, Inc. Equity Incentive Compensation Plan, and
- (7) Registration Statement (Form S-8, No. 333-147380) dated November 14, 2007 pertaining to the Athersys, Inc. Long-Term Incentive Plan;

of our reports dated March 10, 2017, with respect to the consolidated financial statements and schedule of Athersys, Inc. and subsidiaries and the effectiveness of internal control over financial reporting of Athersys, Inc. and subsidiaries included in this Annual Report (Form 10-K) of Athersys, Inc. for the year ended December 31, 2016.

/s/ ERNST & YOUNG LLP

Cleveland, Ohio
March 10, 2017

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each of the undersigned officers and directors of Athersys, Inc., a Delaware corporation, hereby constitutes and appoints of Gil Van Bokkelen, William Lehmann, Jr., and Laura K. Campbell, and each of them, as his true and lawful attorney or attorneys-in-fact, with full power of substitution and revocation, for each of the undersigned and in the name, place, and stead of each of the undersigned, to sign on behalf of each of the undersigned an Annual Report on Form 10-K for the fiscal year ended December 31, 2016 pursuant to Section 13 of the Securities Exchange Act of 1934 and to sign any and all amendments to such Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith including, without limitation, a Form 12b-25 with the Securities and Exchange Commission, granting to said attorney or attorneys-in-fact, and each of them, full power and authority to do so and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorney or attorneys-in-fact or any of them or their substitute or substitutes may lawfully do or cause to be done by virtue thereof.

This power of attorney may be executed in multiple counterparts, each of which shall be deemed an original with respect to the person executing it.

IN WITNESS WHEREOF, the undersigned have hereunto set their hands as of the 11th day of January, 2017.

| <u>Signature</u> | <u>Title</u> |
|---|---|
| /s/ Gil Van Bokkelen _____ Gil Van Bokkelen | Chief Executive Officer and Chairman of the Board of Directors |
| /s/ Laura K. Campbell _____ Laura K. Campbell | Senior Vice President of Finance |
| /s/ John J. Harrington _____ John J. Harrington | Executive Vice President, Chief Scientific Officer and Director |
| /s/ Lorin J. Randall _____ Lorin J. Randall | Director |
| /s/ Jack L. Wyszomierski _____ Jack L. Wyszomierski | Director |
| /s/ Kenneth H. Traub _____ Kenneth H. Traub | Director |
| /s/ Ismail Kola _____ Ismail Kola | Director |
| /s/ Lee E. Babiss _____ Lee E. Babiss | Director |

CERTIFICATIONS

I, Gil Van Bokkelen, certify that:

1. I have reviewed this annual report on Form 10-K of Athersys, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 10, 2017

/s/ Gil Van Bokkelen

Gil Van Bokkelen
Chief Executive Officer and
Chairman of the Board of Directors

CERTIFICATIONS

I, Laura K. Campbell, certify that:

1. I have reviewed this annual report on Form 10-K of Athersys, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 10, 2017

/s/ Laura K. Campbell

Laura K. Campbell

Senior Vice President of Finance

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Athersys, Inc. (the “Company”) on Form 10-K for the year ended December 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer’s knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

Date: March 10, 2017

/s/ Gil Van Bokkelen

Name: Gil Van Bokkelen

Title: Chairman and Chief Executive Officer

/s/ Laura K. Campbell

Name: Laura K. Campbell

Title: Senior Vice President of Finance

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.