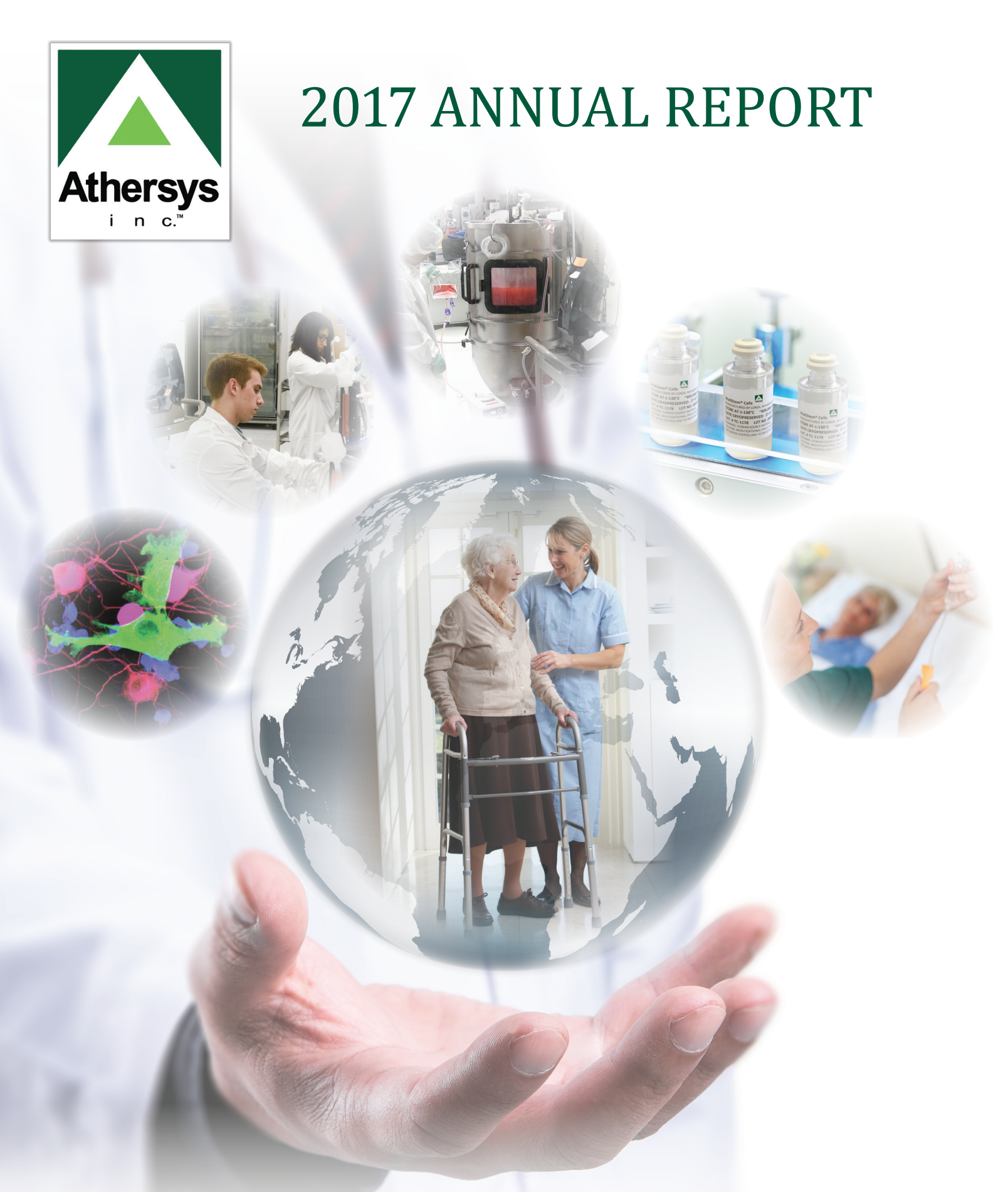
Athersys inc.™

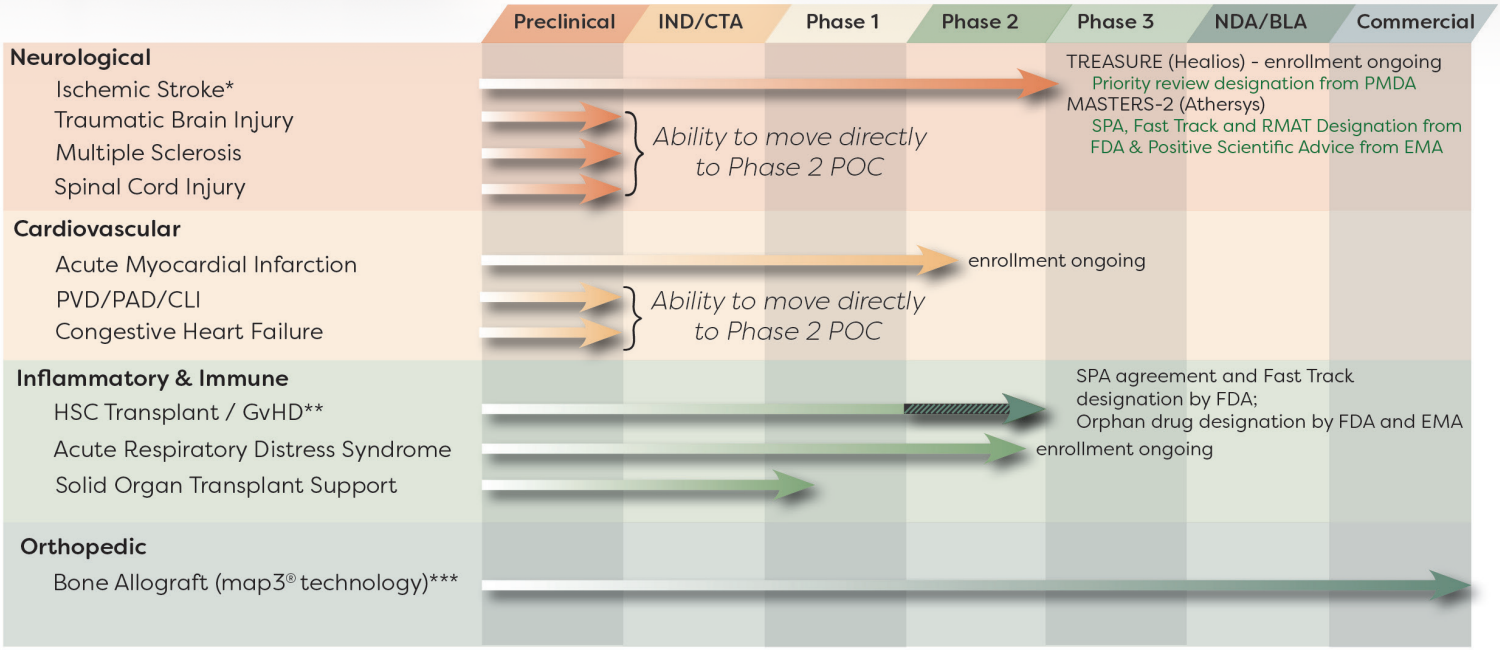
2017 ANNUAL REPORT



Changing the Future of Medicine

Athersys, Inc. *is 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 with several clinical stage programs. Our most advanced program is for the treatment of ischemic stroke, which is currently being evaluated in a registrational trial in Japan, and we are preparing to initiate a Phase 3 clinical trial in North America and Europe under a Special Protocol Assessment, or SPA. 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.*

Developmental Status of Regenerative Medicine Programs



* MASTERS-2 Phase 3 pivotal study under Special Protocol Assessment by FDA; Also, in partnership with Healios, Phase 2/3 clinical trial commenced in Japan under new accelerated regulatory framework and received priority review designation from PMDA.

** Program authorized for Phase 3 pivotal study under Special Protocol Assessment by FDA. Program awarded Orphan Drug status by FDA and EMA, and Fast Track by FDA.

*** Partnership with RTI Surgical, Inc.; map3 is a registered trademark of RTI Surgical, Inc.

To My Fellow Shareholders:

Gil Van Bokkelen, Ph.D.
Chairman and Chief Executive Officer

The past year was a productive one, even with some unexpected challenges over the year. As I write, our company is at an important juncture in its lifecycle – being closer than ever to having a deep and lasting impact on patient health and outcomes following serious injury and illness. We are now in a favorable position for executing our strategy and advancing our MultiStem® product through late-stage clinical development with an eye toward potential commercialization. Our vision for how we can advance or even transform medical care through the successful development of our technologies, such as treating ischemic stroke patients with MultiStem cell therapy, is worthwhile and achievable.

Many of us have experienced serious illness or injury, either through personal health events, or through our family members and loved ones, and dealt with the limitations of current medical care and technology. No matter what the circumstances, this realization can be especially troubling. But, these are precisely the experiences that drive us at Athersys to develop safer and more effective medicines for people who are sick or injured and desperately need help. We are determined to make a difference for patients with our innovative technologies and products.

"Our vision for how we can advance or even transform medical care through the successful development of our technologies, such as treating ischemic stroke patients with MultiStem cell therapy, is worthwhile and achievable."

"But, these are precisely the experiences that drive us at Athersys to develop safer and more effective medicines for people who are sick or injured and desperately need help. We are determined to make a difference for patients with our innovative technologies and products."

Our business opportunity is built on a firm scientific foundation and is focused on our MultiStem products and cell therapy platform directed to significant areas of unmet clinical need and commercial opportunity. Our strategy is concentrated on several core areas: advancing our lead programs through development, registration and into commercialization; further developing our manufacturing advantages, capabilities and capacity to support commercialization; establishing research, operating and business partnerships that materially enhance our ability to, and capacity for, delivering on our mission; and advancing our research through the exploration of other potential applications for MultiStem and our other technologies.

We made some important progress in 2017. On the regulatory front, for instance, we advanced our lead clinical program for treating ischemic stroke through the successful achievement of several important regulatory designations. These include the Sakigake designation in Japan that was obtained early in the year by our partner, HEALIOS K.K., or Healios, and the subsequent Fast Track and Regenerative Medicine Advanced Therapy, or RMAT, designations that we received from the FDA later in the year. Each of these designations serves to shorten and streamline the regulatory and development process, saving us resources and time in the years ahead as we advance this important program.

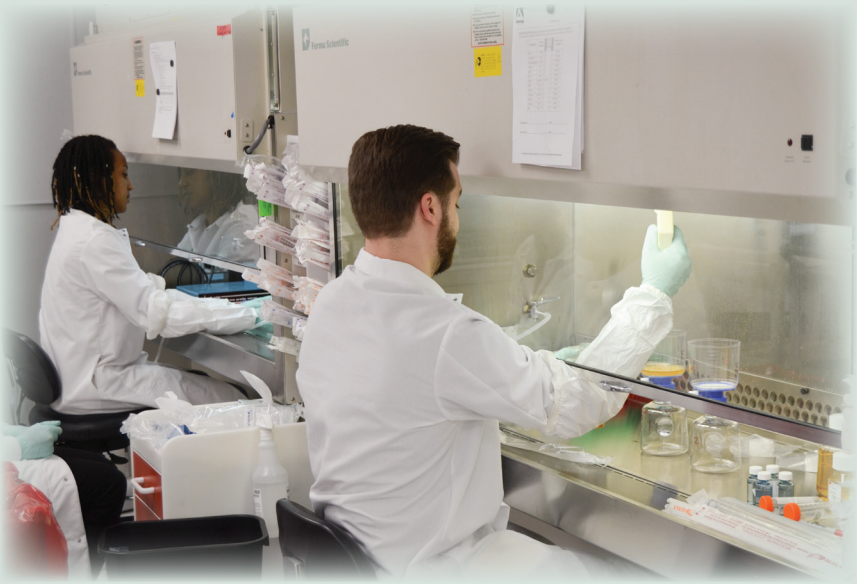
Unfortunately, though, we encountered some unexpected problems at our contract manufacturer that required corrective action during the course of the year. While these problems were beyond our control and had nothing to do with us or our product, they did delay the launch of Healios' ischemic stroke trial in Japan, referred to as the TREASURE study. We worked together with Healios and our contract manufacturer to put in place a plan to enable us to achieve our near-term manufacturing requirements, and Healios was able to dose their first patient for the study in the fourth quarter. Additionally, these manufacturing issues caused us to accelerate our efforts to establish redundant manufacturing capabilities and capacity to support clinical development and initial commercialization, such as through our new alliance with Nikon CeLL innovation, LTD., at their state-of-the-art manufacturing facility in Tokyo. There is still work to be done, but the challenges last year have sharpened our focus on the preparations for the future.

In 2017, we explored opportunities to partner with other businesses to further develop and

commercialize our MultiStem therapy in a variety of areas, including ischemic stroke. As we have noted many times, these types of discussions and evaluations take time, and in considering potential opportunities, we have to balance the near-term benefits against the value creation potential in the medium and longer-term through retaining our development and commercial rights through important milestones. In the end, these efforts paid dividends, as we signed an agreement during the first quarter of 2018 for a planned expansion of our collaboration with Healios. The broadening of our alliance with a capable and motivated partner increases the scope of activities and the potential return to Athersys from successful development, provides Athersys with capital to support key activities, including our pivotal Phase 3 stroke study, MASTERS-2, and preserves our rights and potential value associated with MultiStem development and commercialization in North America and Europe. We look forward to working even more closely with Healios to develop and commercialize MultiStem therapy for treatment of a number of important conditions.

As a result of this progress, our blueprint for moving forward through development, approval and into commercialization of our first MultiStem application, ischemic stroke, over the next several years has become both clearer and more achievable. Its core aspects are straightforward, and success will depend in large part on good execution. First, advance Healios' TREASURE and Athersys' MASTERS-2 studies as efficiently and effectively as possible. Second, continue to build-out the human capabilities and networks to complete development and enable successful commercialization. Third, further develop our manufacturing capabilities and capacity for commercialization, leveraging third-party expertise and resources where appropriate. Fourth, explore opportunities to add capabilities and capital, for example through additional partnerships and collaborations, to ensure that Athersys is well-positioned to optimize the development process and commercial value creation. In addition to these core efforts, our team will be at work on other activities that are intended to enhance the value of our products, cell therapy platform and company overall.

Like many people, I have a passion for sports and enjoy the thrill of competition. When watching sports, I am regularly reminded of certain core principles that are directly related to success. Among these are teamwork, perseverance, focus, hard work, setting clear goals, and maintaining the discipline and relentless determination to achieve something important, even when the

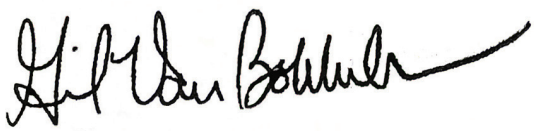


"As a result of this progress, our blueprint for moving forward through development, approval and into commercialization of our first MultiStem application, ischemic stroke, over the next several years has become both clearer and more achievable."

naysayers complain that it can't be done. Some of the most inspirational stories in sports involve teams or individuals that suffer significant challenges or setbacks, or are underestimated by others – they use this as motivation and fuel to accomplish something great. For me, these principles and experiences seem very relevant to us at Athersys. We have a clear vision of what we want to accomplish, and despite occasional setbacks, noise around us and skeptics, we remain intently focused on achieving our goals. And, we understand that we are at our best when we remain disciplined and work together as a cohesive team. Every day we move a step closer to accomplishing our most important objectives, and I firmly believe the best days are still ahead of us.

To all our shareholders, and on behalf of everyone at Athersys and ReGenesys, I thank you for your continued patience and support as we work to realize our goals – and to our partners and collaborators, we deeply appreciate your commitment to our shared vision.

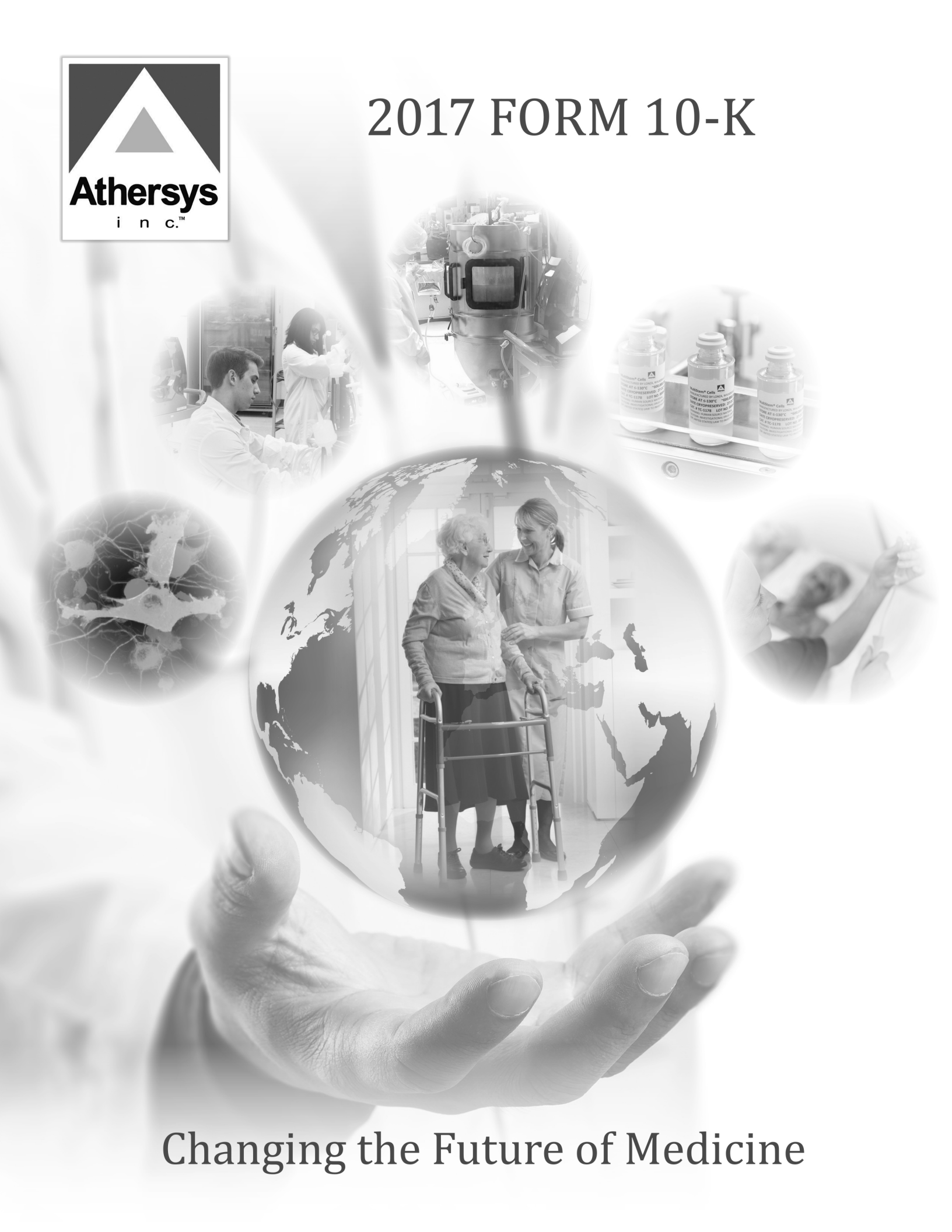
Sincerely,



Gil Van Bokkelen, Ph.D.
Chairman and Chief Executive Officer

Athersys inc.™

2017 FORM 10-K



Changing the Future of Medicine

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, 2017

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	**20-4864095**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3201 Carnegie Avenue, Cleveland, Ohio	**44115-2634**
(Address of principal executive offices)	**(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	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

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, 2017, 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 $1.51 of such stock as quoted on the NASDAQ Capital Market on such date) held by non-affiliates of the registrant was approximately $161.5 million.

The registrant had 125,830,331 shares of common stock outstanding on March 7, 2018.

Documents Incorporated By Reference.

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the registrant's definitive proxy statement with respect to the 2018 annual meeting of stockholders.

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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 with several clinical stage programs. Our most advanced program is for the treatment of ischemic stroke, which is currently being evaluated in a registrational trial in Japan, and we are preparing to initiate a Phase 3 clinical trial in North America and Europe under a Special Protocol Assessment, or SPA. 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 has shown the potential 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 conventional 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 be durable based on prior clinical results.

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 or injury, 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 development, targeting areas of significant medical need and 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 the results from prior studies. While the study did not achieve the primary and component secondary endpoints for the intent-to-treat population, 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, or ICU. In addition, analyses show that patients who received MultiStem treatment earlier in the study’s treatment window (24 to 36 hours post-stroke, in accordance with the original study protocol) had better recovery in comparison to placebo. Furthermore, analysis of biomarker data obtained from samples of study subjects indicated that MultiStem treatment reduces post-stroke inflammation compared to placebo, and results suggest that this effect is more pronounced for subjects receiving MultiStem earlier within the treatment window. 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 (i.e. receiving an "Excellent" score 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 treatment window would make this therapy available to most stroke patients, in contrast to other therapies (e.g., tPA), which have substantially shorter treatment windows.

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. This collaboration may also 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, as well as milestones and tiered double-digit royalties.

In March 2018, we entered into a binding letter of intent (the "LOI") with Healios to significantly expand Healios' license to develop MultiStem products. Under the terms of the LOI, we and Healios will work to execute the agreements necessary to expand the existing collaboration by April 30, 2018. If the expansion is consummated, Healios would, among other things, (i) expand its license in Japan to include ARDS, including idiopathic pulmonary fibrosis ("ARDS Field"), trauma and use of MultiStem for organ buds for all organ diseases, (ii) obtain a worldwide exclusive license for use of MultiStem product to treat certain ophthalmological indications, and (iii) obtain an exclusive option to a license to develop and commercialize MultiStem products for ischemic stroke, the ARDS Field and trauma in China. In exchange, we would be entitled to receive payments of $35 million ($10 million of which is guaranteed to be paid to us), as well as additional possible payments, including milestones and royalties. If the expansion agreements are entered into and, thereafter, Healios elects to exercise its option for the license in China, Healios would pay us license fees, milestone payments and escalating royalties or profit-sharing for each indication in China.

Also in March 2018, Healios purchased 12,000,000 shares of our common stock and a warrant to purchase up to an additional 20,000,000 shares of common stock for $21,100,000, or approximately $1.76 per share. The warrant does not become effective until the expansion agreements are effective, has a term that expires in September 2020 (subject to a potential nine-month extension), includes both fixed and floating exercise price mechanisms, and is capped such that in no event will Healios own more than 19.9% of our common stock. We and Healios have entered into an investor rights agreement that governs certain rights and obligations relating to Healios' ownership of our common stock, including rights regarding Board of Director nominees.

Prior to entering into the partnership with Healios, we conducted a series of meetings with PMDA to prepare for subsequent clinical development in Japan. Since our partnership was established, we have worked closely with Healios to support their development efforts in Japan. In 2016, the PMDA authorized the Clinical Trial Notification, or CTN, for Healios' Phase 2/3 trial of MultiStem (HLCM051), entitled "Treatment Evaluation of Acute Stroke for Using in Regenerative Cell Elements," or TREASURE. This clinical trial, which could lead to registration, has since been initiated and is currently enrolling patients. Japan's Regenerative Medicine regulatory framework is designed to enable rapid development of qualified regenerative medicine therapies by providing either conditional or full approval of qualified therapies. Under the new framework, this program has been awarded the "Sakigake" designation by PMDA, which is designed to expedite regulatory review and development, and is analogous to Fast Track designation from the FDA.

In addition to the ongoing development in Japan, following the completion of our Phase 2 trial, or MASTERS-1, we have also advanced our development efforts in North America and Europe by engaging in subsequent discussions with the FDA, EMA and other regulators. 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. This program has subsequently received Fast Track designation from the FDA, as well as the Regenerative Medicine Advanced Therapy, or RMAT, designation, which the FDA has described as analogous to Breakthrough Therapy designation that exists for non-regenerative medicine and advanced therapies. We believe these designations could accelerate the development, regulatory review and subsequent commercialization of products like MultiStem cell therapy for ischemic stroke, if future clinical evaluation demonstrates appropriate safety and therapeutic effectiveness.

In addition to our program for ischemic stroke, we are currently 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, more commonly referred to as a "heart attack". This trial is ongoing, and has been funded in part by a grant from the National Institutes of Health. 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.

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, which is associated with a high rate of death and disability, making it an area of high unmet clinical need with high treatment costs. The study is currently enrolling patients and has been supported in part by a grant from Innovate UK.

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 or SPA, agreement 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.

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.

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 that we are aware of, along with full reimbursement of those products, and we and Healios intend to utilize this framework.

In addition to our MultiStem clinical programs, we have other earlier-stage 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, and are currently evaluating partnering opportunities related to certain programs. For certain programs we may elect to fund further development in certain markets in order to maximize value for our shareholders.

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 where we believe there is a substantial commercial opportunity. The key elements of our strategy are outlined below:

- *Advance our Lead Programs through Clinical Development to Registration and Commercialization*. We are focused on the design and execution of late-stage clinical studies (e.g., ischemic stroke) intended to enable product registration in major markets. We are also engaged in activities intended to enable effective commercialization, e.g., preparation for scaling-up manufacturing. We may partner with other companies to complete such development and preparation, and to market the product upon regulatory approval.

- *Efficiently Conduct Clinical Development to Establish Clinical Proof of Concept and Biological Activity for other Product Candidates.* We continue to conduct 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, EMA and PMDA regulatory agencies have resulted in productive interactions and important designations 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 MultiStem cell therapy is the *ex vivo* expansion capacity of the cells that comprise the product. This enables large-scale production of the clinical product, which is associated with 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, through our internal capabilities and efforts, and working with contract manufacturers, where appropriate. We are focused on development and optimization of new and proprietary manufacturing techniques and the pharmacy-to-bedside approach to support late-stage development and commercialization of the MultiStem product. Additionally, we will continue to refine our understanding of our products' activities and mechanisms of action 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 and injury, 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 245 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 2016. We are actively engaged in advancing the next stage of clinical development of this program, both independently and with Healios.

  In 2016, we announced that we received agreement from the U.S. Food and Drug Administration, or FDA, under a Special Protocol Assessment, or SPA, for the design and planned analysis of a pivotal Phase 3 clinical trial of MultiStem cell therapy for the treatment of ischemic stroke, referred to as MASTERS-2. 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 can address objectives in support of a regulatory submission for approval of the MultiStem product for treating ischemic stroke patients if the trial is successful. In May 2017, we announced that the FDA granted us Fast Track designation for our clinical product for the treatment of ischemic stroke. Such designation for a new biologic product means that the FDA will take such actions as are appropriate to expedite the development and review of our application to approve the product, and specifically, under Fast Track designation, the program becomes eligible for rolling submission, accelerated approval and priority review of the biologics license application, facilitating a timely regulatory review. Also, in August 2017, we announced that the design of MASTERS-2 received a Final Scientific Advice positive opinion from the European Medicines Agency, or EMA, representing EMA's agreement that successful results from the trial could result in registration and marketing approval of the MultiStem therapy. This positive opinion provides further alignment among the key regulators regarding potential commercialization of the MultiStem product upon success of this single pivotal trial. In October 2017, we received the RMAT designation from the FDA, which was established under the 21st Century Cures Legislation. The RMAT designation may be obtained for eligible cell therapy and other regenerative medicine and advanced therapies when the FDA agrees that preliminary clinical evidence indicates that the therapy has demonstrated the potential to address unmet medical needs for a serious or life threatening disease or condition. The RMAT designation is the equivalent of the Breakthrough Therapy designation that exists for non-regenerative medicine products, and designated products benefit from all Breakthrough Therapy features. The designation enables sponsors to discuss with the FDA multidisciplinary strategic development plans, including expediting manufacturing development plans for commercialization to support priority review and accelerated approval.

  In September 2016, we announced the successful completion of the Pharmaceutical and Medical Devices Agency, or PMDA, review of Healios' Clinical Trial Notification, or 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, or IND, application under the regulatory system used in the United States, or U.S. This 220 patient randomized, double blind, placebo controlled clinical trial is being conducted in Japan as part of a partnership and license agreement between Healios and Athersys. This partnership is focused on the development and commercialization of MultiStem in Japan for the treatment of ischemic stroke, and potentially other indications.

  Our MASTERS-2 clinical trial is 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 $\leq$1, NIHSS $\leq$1, and Barthel Index $\geq$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.

Healios' TREASURE study in Japan is being 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. The TREASURE study was initiated earlier in 2017, though interruption in media supply at our contract manufacturer affected manufacturing of the MultiStem product and had slowed the launch of the Japan study. The TREASURE study was reinitiated in November 2017, following a brief interruption to resupply placebo that was out of specification and is currently enrolling patients. Further interruptions in material supply or product manufacturing could constrain product supply and slow the progress of the clinical study.

We are preparing to launch our MASTERS-2 clinical trial, including site selection and the manufacture of clinical product, and intend to initiate the study in the second quarter of 2018 beginning with specific high-enrolling sites. We look forward to launching the study and using the accelerated pathway afforded to us by the regulators in the U.S., Europe and Japan upon study completion.

• Acute Myocardial Infarction: We are conducting an ongoing Phase 2 clinical study in the U.S. for the administration of MultiStem cell therapy to patients that have suffered an acute myocardial infarction, or AMI. In a previously completed Phase 1 clinical study, we evaluated the administration of MultiStem to patients that suffered an AMI. 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 support of the advancement of this clinical program, and we launched a double-blind, sham-controlled Phase 2 clinical study, evaluating the safety and efficacy of MultiStem treatment in subjects who have experienced a myocardial infarction. The study is currently enrolling patients and is being conducted at leading cardiovascular centers. We continue to take steps to improve enrollment rates that have been below our expectations and will provide updates regarding the conduct and completion of the study, as appropriate.

• Acute Respiratory Distress Syndrome: We initiated a clinical study for the treatment of acute respiratory distress syndrome, or ARDS, in the United Kingdom and in the U.S. We 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. 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 and cared for in the ICU. ARDS can be triggered by pneumonia, sepsis, trauma or for other reasons, and represents a major cause of morbidity and mortality in the critical care setting. The Phase 1/2 clinical trial is ongoing, and our objective is to complete this study in 2018.

• 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 graft-vs-host disease, or GvHD. Data from the study 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, and 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 Scientific Advice opinion from EMA through the SA procedure, as well as a SPA designation from the FDA. Currently, this program is staged 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.

MultiStem therapy has been evaluated in other disease areas, such as inflammatory bowel disease with a collaborator, solid organ transplant in an investigator-sponsored study, and a limited number of compassionate use cases.

While development of our clinical programs for human health indications remains our priority, based on our research to date and work performed at our wholly-owned subsidiary, ReGenesys, we are also evaluating our cell therapy for use in treating diseases and conditions in the animal health area. We have demonstrated in preclinical animal health models that our 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 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 also engage 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.

While 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 good manufacturing practices, we will continue to rely on third party manufacturers to make our MultiStem product for clinical trials and eventual 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; provided, that, if we fail to perform our responsibilities to supply clinical trial product to Healios, then under certain circumstances, we may be required to grant Healios a license to make the product solely for use in the licensed field in Japan.

In March 2018, we entered into the LOI with Healios to significantly expand Healios' license to develop MultiStem products and are working to execute the agreements necessary to expand the existing collaboration by April 30, 2018. If the expansion is consummated, Healios would, among other things, (i) expand its license in Japan to include the ARDS Field, trauma and use of MultiStem for organ buds for all organ diseases, (ii) obtain a worldwide exclusive license for use of MultiStem product to treat certain ophthalmological indications, and (iii) obtain an exclusive option to a license to develop and commercialize MultiStem products for ischemic stroke, the ARDS Field and trauma in China.

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 continue to receive royalty revenue from product sales and may receive other payments from time to time upon the successful achievement of certain commercial milestones. In 2017, we received a $1.0 million payment associated with achievement of a commercial milestone. Also, in the fourth quarter of 2017, our royalty rate increased as a result of reaching a milestone for product sales.

We have also developed other earlier stage programs targeted at indications with significant unmet needs. We may elect to enter into partnerships to advance the development of these programs, or pursue independent development.

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 even millions, of individual doses, representing a yield far greater than we believe 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 17.9% of all economic activity in 2016, or about $3.3 trillion dollars, annually according to the National Health Expenditure Accounts and the Centers for Medicaid and Medicare Services. 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 from the Department of Health and Human Services shows that 71% 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 patients suffering from severe, treatment refractory ulcerative colitis.

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 quality of life and 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. This narrow time window is essential to minimize potential risks to the patient, 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, MASTERS-1, 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 in the study's treatment window (i.e., 24 to 36 hours post-stroke, as specified in the original study protocol) 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, in our FDA-approved MASTERS-2 Phase 3 study, which has been authorized by the FDA (under a SPA) and EMA. If proven effective, this treatment would make therapy available to most stroke patients, in contrast to other therapies (e.g., tPA), which have substantially shorter treatment windows.

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 2.8 million cases of TBI are seen in the United States each year. 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 CDC also estimates the annual direct and indirect costs for TBI are approximately $76.5 billion a year. 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. With grant funding from the NIH, we further advanced 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 are also conducting preclinical work exploring the application of MultiStem treatment in other neurological indications and have presented data 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 of 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.

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 790,000 people suffer a heart attack each year, and approximately 6.5 million individuals in the United States were suffering from heart failure in 2014, according to the American Heart Association 2017 Statistical Update. Another 8.5 million people suffer from peripheral arterial disease, which is associated with significant morbidity and mortality. In addition, in 2014 (latest year available), there were approximately 807,775 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*.

We are currently conducting a Phase 2 clinical study for the administration of MultiStem cell therapy to patients that have suffered an AMI, which has been supported by a grant from the NIH, 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 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 U. S. and Japan, alone. We, through our subsidiary, Athersys Limited, are conducting a Phase 1/2 clinical study evaluating the administration of MultiStem cell therapy to ARDS patients, which has been partially supported by grant funding from Innovate UK. We initiated this study in 2016 in both the UK and the United States, and it is currently enrolling patients. We intend to complete this study in 2018.

Another area of focus is the use of MultiStem cell therapy 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.

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 and, we announced the results from the trial in 2012. 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, and 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 2015, the proposed registration study received SPA 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 BVBA, 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 for 2017 to 2027 was estimated to be valued at approximately $55 billion and is expected to grow at a compound annual growth rate of more than 4.3% 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.

Collaborations and Partnerships

Healios

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 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.

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. 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 ischemic stroke indication, we may receive 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.

In January 2017, we signed a clinical trial supply agreement, which is consistent with the license agreement, in preparation for delivering the planned manufacturing services for Healios' clinical trial in Japan. The clinical trial supply agreement was amended in July 2017 and clarifies the operational elements, terms and cost-sharing arrangement associated with our supply of clinical material and related adjustments to certain future milestone payments.

In September 2017, we entered into a services agreement with Healios, in which Healios provides financial support to establish a contract manufacturer in Japan to produce product for Healios. Also in September 2017, we amended the Healios Agreement to confer to Healios a limited license to manufacture MultiStem in the event that we are acquired by a third-party.

In March 2018, we entered into the LOI with Healios to significantly expand Healios' license to develop MultiStem products and are working to execute the agreements necessary to expand the existing collaboration by April 30, 2018. If the expansion is consummated, Healios would, among other things, (i) expand its license in Japan to include the ARDS Field, trauma and use of MultiStem for organ buds for all organ diseases, (ii) obtain a worldwide exclusive license for use of MultiStem product to treat certain ophthalmological indications, and (iii) obtain an exclusive option to a license to develop and commercialize MultiStem products for ischemic stroke, the ARDS Field and trauma in China. In exchange, we would be entitled to receive payments of $35 million ($10 million of which is guaranteed to be paid to us), as well as additional possible payments, including milestones and royalties. If the expansion agreements are entered into and, thereafter, Healios elects to exercise its option for the license in China, Healios would pay us license fees, milestone payments and escalating royalties or profit-sharing for each indication in China.

Also in March 2018, Healios purchased 12,000,000 shares of our common stock and a warrant to purchase up to an additional 20,000,000 shares of common stock for $21,100,000, or approximately $1.76 per share. The warrant does not become effective until the expansion agreements are effective.

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 and received $5.0 million of license fees. We are eligible to receive an additional $34.5 million in remaining cash payments upon the successful achievement of certain commercial milestones, after the first commercial milestone payment of $1.0 million occurred in 2017, though there can be no assurance that further milestones will be achieved. 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, and in the fourth quarter of 2017, our royalty rate increased as a result of reaching a milestone for product sales, although there can be no assurances that further such milestones resulting in increased royalty rates will be achieved. 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.

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.

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. We subsequently further developed this technology, including refining and establishing proprietary methods related to 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, 2017, 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 maintains active programs using our cell lines as of December 31, 2017 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, or 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 eventual 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 inspection 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 and commercial activities. Furthermore, material supply constraints could result in production delays. We attempt to mitigate risk 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 (recently acquired by Takeda), 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 245 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 over 220 issued patents (of which 28 are United States patents) and more than 150 global patent applications around our stem cell technology and MultiStem product platform. This includes 27 United States patents and more than 185 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 2034 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 also have established a broad intellectual property portfolio related to our small molecule product candidates, functional genomics, and other technologies, with over 25 global patents with claims directed to compositions, methods of making, and methods of using our candidates and technologies, among other claims.

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 and Europe involving a third party's technology developed after the MAPC technology, which ultimately resulted in a license agreement favorable to the Company as noted below. 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.

In October 2017, we entered into an agreement with Garnet BioTherapeutics, Inc. ("Garnet") to settle longstanding intellectual property disagreements between the parties. Over the past several years, we have been involved in several proceedings in the United States and Europe involving Garnet, focused on stem cell technologies. As part of the agreement, we have been granted a license to Garnet patents and applications that have been at the core of the intellectual property dispute, for use related to the treatment or prevention of disease or conditions using cells. In return, we have agreed not to enforce our intellectual property rights against Garnet with respect to therapeutic agents derived from cells (but we fully retain our ability to enforce our rights with respect to cells used as therapy). We also agreed not to further challenge the patentability or validity of certain Garnet applications or patents (noting that we have been granted a license, as described above). We initially paid Garnet $500,000 and issued 1,000,000 shares of our common stock in connection with the execution of the agreement, and agreed to pay an additional $250,000 per quarter over one year. Additionally, we will issue 500,000 shares of common stock upon issuance of a patent from the Garnet patent applications at the core of the dispute. There will be no royalty payments or milestone payments to Garnet associated with the development and commercialization of our cell therapy products or other payments to Garnet related to the settlement agreement.

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 $27.8 million in 2017, $24.8 million in 2016 and $21.3 million in 2015.

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;
- 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 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, 2017, we employed 66 full-time employees, including 17 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, which 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 $32.2 million in 2017, $15.3 million in 2016 and $16.4 million in 2015. As of December 31, 2017, we had an accumulated deficit of $350.6 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 $24.0 million in 2017, $10.9 million in 2016 and $13.8 million in 2015.

At December 31, 2017, we had $29.3 million of cash and cash equivalents, and in January and February 2018, we added $5.5 million to our cash position through the issuance of common stock through our equity purchase arrangement with Aspire Capital Fund, LLC, or Aspire Capital. 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 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 arrangement with 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 over $100 million available under the arrangement as of February 28, 2018, 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 candidates, 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 upon consummation of the proposed expansion announced in March 2018, 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 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 GMP established by the FDA or similar regulations in other countries. Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured MultiStem ourselves. Although we are primarily responsible for regulatory compliance with respect to the manufacture of MultiStem product, we rely on the third party to manufacture the product as cost effectively as possible and to ensure product quality. Additionally, the production of our MultiStem product requires the availability of raw materials that are sourced through a limited number of suppliers. The failure of third-party manufacturers or suppliers to perform adequately or the termination of our arrangements with any of them may adversely affect our business.

These third parties may not deliver sufficient quantities of our MultiStem product, manufacture MultiStem product in accordance with specifications and cost expectations, 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 and commercial activities. Furthermore, our third-party manufacturers may have disruptions in their business operations as a result of business or strategic decisions or due to economic difficulties facing their businesses and could cease operations entirely. The number of third party manufacturers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative manufacturing arrangements.

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 fails to meet our product specifications or experiences a significant problem that could result in a delay or interruption in the supply of product materials to us, our clinical trials, business and reputation could be severely impacted. 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 senior executives such as 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 U.S. 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, Stem Cells Inc., Cytori and Pluristem. 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 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 proceedings in the United States and Europe with a third party focused on a technology developed after the MAPC technology. Ultimately, we reached a settlement agreement with and obtained a license from this third party, positioning us advantageously with respect to the achievement of our business objectives. 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.

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. Furthermore, we are subject to an increasing number of data privacy and data protection laws in both the U.S. and abroad. Failure to comply with these regulations could result in fines, penalties or significant legal liability.

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, 2017, we had U.S. federal net operating loss and research and development tax credit carryforwards of approximately $136.6 million and $7.3 million, 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 2021 and 2037. We also had foreign net operating loss carryforwards of approximately $19.9 million. Such foreign net operating loss carryforwards do not expire. We also had state and city net operating loss carryforwards aggregating approximately $69.4 million. Such operating losses may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2018 and 2037.

Our ability to utilize our U.S. federal 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, or the Code, as a result of our equity offering that occurred in October 2012. Similar limitations may apply for state and local tax purposes. We generated U.S. federal net operating loss carryforwards of $99.9 million, research and development tax credits of $7.3 million, and state and local net operating loss carryforwards of $69.4 million since 2012 through December 31, 2017.

Our ability to utilize tax attributes, including those that are not part of the Section 382 Limited Attributes may also be limited if we experience an "ownership change," for purposes of Section 382 of the Code. 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. Sales of our common stock to Aspire Capital pursuant to our equity purchase arrangement, in combination with other issuances or sales of our common stock (including any sales of common stock by Aspire Capital and 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. We will update our analysis under Section 382 of the Code prior to using our tax attributes.

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 2019, and we intend to renew our agreement. 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 2018, and we have an option to renew annually through July 2022. The annual rent in Belgium is approximately $185,000 and is subject to adjustments based on an inflationary index. Our total rent expense for all properties was $477,000 in 2017.

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: 57

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 serves on the board of the Alliance for Regenerative Medicine (and served as chairman 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: 50

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.

William (BJ) Lehmann, Jr., J.D.
Age: 52

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 a variety of industries. 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: 54

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.

	High	Low
Year ended December 31, 2017:		
Fourth Quarter	$2.45	$1.65
Third Quarter	$2.55	$1.46
Second Quarter	$1.76	$1.39
First Quarter	$1.90	$1.09
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

Holders

As of February 28, 2018, there were approximately 511 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.

Unregistered Sales

During the quarter ended December 31, 2017, we sold an aggregate of 4,050,000 shares of common stock to Aspire Capital under our equity purchase agreement, generating aggregate proceeds of $7.4 million. Each issuance of these unregistered shares qualifies as an exempt transaction pursuant to Section 4(2) of the Securities Act of 1933. Each issuance qualified for exemption under Section 4(2) of the Securities Act of 1933 because none involved a public offering. Each offering was not a public offering due to the number of persons involved, the manner of the issuance and the number of securities issued. In addition, in each case Aspire Capital had the necessary investment intent.

In October 2017, we entered into an agreement with Garnet to settle longstanding intellectual property disagreements between the parties. As part of the agreement, we have been granted a license to Garnet patents and applications that have been at the core of the intellectual property dispute, for use related to the treatment or prevention of disease or conditions using cells. In return, we have agreed not to enforce our intellectual property rights against Garnet with respect to therapeutic agents derived from cells (but we fully retain our ability to enforce our rights with respect to cells used as therapy). We also agreed not to further challenge the patentability or validity of certain Garnet applications or patents (noting that we have been granted a license, as described above). We initially paid Garnet $500,000 and issued 1,000,000 shares of our common stock in connection with the execution of the agreement, and agreed to pay an additional $250,000 per quarter over one year. Additionally, we will issue 500,000 shares of common stock upon issuance of a patent from the Garnet patent applications at the core of the dispute.

ITEM 6. SELECTED FINANCIAL DATA

(in thousands, except per share data)

	Year Ended December 31,				
	2017	2016	2015	2014	2013
Consolidated Statement of Operations Data:					
Revenues:					
Contract revenue	$ 2,843	$ 16,238	$ 10,298	$ 286	$ 755
Grant revenue	865	1,109	1,650	1,337	1,683
Total revenues	3,708	17,347	11,948	1,623	2,438
Costs and expenses:					
Research and development	27,841	24,838	21,316	23,366	20,484
General and administrative	8,466	7,835	7,536	6,909	6,065
Depreciation	684	382	267	360	346
Total costs and expenses	36,991	33,055	29,119	30,635	26,895
Gain from insurance proceeds, net	—	682	—	—	—
Loss from operations	(33,283)	(15,026)	(17,171)	(29,012)	(24,457)
Other income (expense):					
Income (expense) from change in fair value of warrants	728	(557)	772	6,591	(6,324)
Other income (expense), net	314	246	(23)	339	38
Net loss	**$ (32,241)**	**$(15,337)**	**$(16,422)**	**$(22,082)**	**$(30,743)**
Net loss per share, basic	**$ (0.29)**	**$ (0.18)**	**$ (0.20)**	**$ (0.29)**	**$ (0.53)**
Weighted average shares outstanding, basic	112,053	84,715	82,144	76,955	57,675
Net loss per share, diluted	**$ (0.29)**	**$ (0.18)**	**$ (0.20)**	**$ (0.31)**	**$ (0.53)**
Weighted average shares outstanding, diluted	112,053	84,715	82,851	78,541	57,675

	December 31,				
	2017	2016	2015	2014	2013
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 29,316	$ 14,753	$ 23,027	$ 26,127	$ 31,948
Working capital, excluding note payable	21,107	9,405	19,251	22,556	28,487
Total assets	33,593	19,060	25,129	28,718	34,188
Warrant liabilities and note payable	—	1,004	839	3,131	9,999
Total stockholders' equity	23,376	11,181	19,724	20,895	19,821

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 with several clinical stage programs. 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 2016. We are actively engaged in advancing the next stage of clinical development of this program, both independently and with Healios.

In 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, referred to as MASTERS-2. 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 can address objectives in support of a regulatory submission for approval of the MultiStem product for treating ischemic stroke patients, if the trial is successful. In May 2017, we announced that the FDA granted us Fast Track designation for our clinical product for the treatment of ischemic stroke. Such designation for a new biologic product means that the FDA will take such actions as are appropriate to expedite the development and review of our application to approve the product, and specifically, under Fast Track designation, the program becomes eligible for rolling submission, accelerated approval and priority review of the biologics license application, facilitating a timely regulatory review. Also, in August 2017, we announced that the design of MASTERS-2 received a Final Scientific Advice positive opinion from EMA, representing EMA's agreement that successful results from the trial could result in registration and marketing approval of the MultiStem therapy. This positive opinion provides further alignment among the key regulators regarding potential commercialization of the MultiStem product upon success of this single pivotal trial. In October 2017, we received the RMAT, designation from the FDA, which was established under the 21st Century Cures Legislation. The RMAT designation may be obtained for eligible cell therapy and other regenerative medicine and advanced therapies when the FDA agrees that preliminary clinical evidence indicates that the therapy has demonstrated the potential to address unmet medical needs for a serious or life threatening disease or condition. The RMAT designation is the equivalent of the Breakthrough Therapy designation that exists for non-regenerative medicine products, and designated products benefit from all Breakthrough Therapy features. The designation enables sponsors to discuss with the FDA multidisciplinary strategic development plans, including expediting manufacturing development plans for commercialization to support priority review and accelerated approval.

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, application under the regulatory system used in the U.S. This 220 patient randomized, double blind, placebo controlled clinical trial is being conducted in Japan as part of a partnership and license agreement between Healios and Athersys. This partnership is focused on the development and commercialization of MultiStem in Japan for the treatment of ischemic stroke, and potentially other indications.

Our MASTERS-2 clinical trial is 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 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.

Healios' TREASURE study in Japan is being 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. The TREASURE study was initiated earlier in 2017, though interruption in media supply at our contract manufacturer affected manufacturing of the MultiStem product and had slowed the launch of the Japan study. The TREASURE study was reinitiated in November 2017, following a brief interruption to resupply placebo that was out of specification, and is currently enrolling patients. Further interruptions in material supply or product manufacturing could constrain product supply and slow the progress of the clinical study.

We are preparing to launch our MASTERS-2 clinical trial, including site selection and the manufacture of clinical product, and intend to initiate the study in the second quarter of 2018 beginning with specific high-enrolling sites. We look forward to launching the study and using the accelerated pathway afforded to us by the regulators in the U.S., Europe and Japan upon study completion.

• Acute Myocardial Infarction: We are conducting an ongoing Phase 2 clinical study in the U.S. for the administration of MultiStem cell therapy to patients that have suffered an AMI. In a previously completed Phase 1 clinical study, we evaluated the administration of MultiStem to patients that suffered an AMI. 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 support of the advancement of this clinical program, and we launched a double-blind, sham-controlled Phase 2 clinical study, evaluating the safety and efficacy of MultiStem treatment in subjects who have experienced a myocardial infarction. The study is currently enrolling patients and is being conducted at leading cardiovascular centers. We continue to take steps to improve enrollment rates that have been below our expectations and will provide updates regarding the conduct and completion of the study, as appropriate.

• Acute Respiratory Distress Syndrome: We have also initiated a clinical study for the treatment of ARDS in the U K and in the U.S. We 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. 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 and cared for in the ICU. ARDS can be triggered by pneumonia, sepsis, trauma or for other reasons, and represents a major cause of morbidity and mortality in the critical care setting. The Phase 1/2 clinical trial is ongoing, and our objective is to complete this study in 2018.

• 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. Data from the study 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, and 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 Scientific Advice opinion from EMA through the SA procedure, as well as a SPA designation from the FDA. Currently, this program is staged 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.

MultiStem therapy has been evaluated in other disease areas, such as inflammatory bowel disease with a collaborator, solid organ transplant in an investigator-sponsored study, and a limited number of compassionate use cases.

While development of our clinical programs for human health indications remains our priority, based on our research to date and work performed at our wholly-owned subsidiary, ReGenesys, we are also evaluating our cell therapy for use in treating diseases and conditions in the animal health area. We have demonstrated in preclinical animal health models that our 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 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 also engage 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.

While 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 good manufacturing practices, we will continue to rely on third-party manufacturers to make our MultiStem product for clinical trials and eventual 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; provided, that, if we fail to perform our responsibilities to supply clinical trial product to Healios, then under certain circumstances, we may be required to grant Healios a license to make the product solely for use in the licensed field in Japan.

In March 2018, we entered into the LOI with Healios to significantly expand Healios' license to develop MultiStem products and are working to execute the agreements necessary to expand the existing collaboration by April 30, 2018. If the expansion is consummated, Healios would, among other things, (i) expand its license in Japan to include the ARDS Field, trauma and use of MultiStem for organ buds for all organ diseases, (ii) obtain a worldwide exclusive license for use of MultiStem product to treat certain ophthalmological indications, and (iii) obtain an exclusive option to a license to develop and commercialize MultiStem products for ischemic stroke, the ARDS Field and trauma in China.

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 continue to receive royalty revenue from product sales and may receive other payments from time to time upon the successful achievement of certain commercial milestones. In 2017, we received a $1.0 million payment associated with achievement of a commercial milestone. Also, in the fourth quarter of 2017, our royalty rate increased as a result of reaching a milestone for product sales.

We have also developed other earlier stage programs targeted at indications with significant unmet needs. We may elect to enter into partnerships to advance the development of these programs, or pursue independent development.

Financial

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. 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.

For the ischemic stroke indication, we may receive additional success-based development, regulatory approval and sales milestones of $225 million in aggregate, and tiered royalties on product sales that start in the low double digits and increase incrementally into the high teens depending on net sales levels. Additionally, we receive payments for product supplied to Healios under a manufacturing supply agreement, which is initially focused on clinical product supply, and in 2017, we agreed to a cost-sharing arrangement with Healios for clinical product for its TREASURE trial in Japan that may impact the amount of proceeds we receive from future milestones. We began receiving cost-sharing proceeds late in 2017.

In addition, in September 2017, we entered into a services agreement with Healios, in which Healios provides financial support to establish a contract manufacturer in Japan to produce product for Healios. The services under this arrangement commenced in the fourth quarter of 2017.

In connection with the March 2018 LOI, we would be entitled to receive payments of $35 million ($10 million of which is guaranteed to be paid to us), as well as additional possible payments, including milestones and royalties. If the expansion agreements are entered into and, thereafter, Healios elects to exercise its option for the license in China, Healios would pay us license fees, milestone payments and escalating royalties or profit-sharing for each indication in China.

Also in March 2018, Healios purchased 12,000,000 shares of our common stock and a warrant to purchase up to an additional 20,000,000 shares of common stock for $21,100,000, or approximately $1.76 per share. The warrant does not become effective until the expansion agreements are effective.

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.

We have in place an equity purchase arrangement 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 recently renewed in February 2018, we can elect to sell to Aspire Capital up to an additional $100 million of shares of common stock under the agreement. Furthermore, the prior facility that was entered into in December 2015 has approximately 2.0 million shares that remain available to us for issuance. The terms of the 2018 equity facility are similar to the previous arrangements, and we issued 450,000 shares of our common stock to Aspire Capital as a commitment fee in February 2018 and filed a registration statement for the resale of 24,700,000 shares of common stock in connection with the new equity facility. Also in connection with the new equity facility, Aspire invested $1.0 million to purchase 500,000 shares of common stock at $2.00 per share. During the quarter ended December 31, 2017, 4,050,000 shares were sold under the Aspire Capital equity purchase agreement at an average price of $1.83, and during the year ended December 31, 2017, we sold 9,400,000 shares to Aspire Capital at an average price of $1.75. In addition, in January and February 2018, we generated approximately $4.5 million of proceeds from the use of our equity facility.

During the year ended December 31, 2017 and 2016, we received proceeds of approximately $1.9 million and $0.2 million, respectively, from the exercise of warrants. All of our previously outstanding warrants were either exercised prior to expiration or expired in March 2017, and we no longer have any warrants outstanding.

In 2016, a flood caused damage to our primary facilities that required the reconstruction of certain laboratory space and was covered by insurance at replacement cost. Insurance recovery proceeds of $0.7 million were received in 2016. In February 2018, we received an additional $0.3 million in insurance proceeds.

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, 2017 Compared to Year Ended December 31, 2016

Revenues. Revenues decreased to $3.7 million for the year ended December 31, 2017 from $17.3 million in 2016, 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, partially offset by 2017 revenues, including a $1.0 million milestone payment from RTI and proceeds from our collaboration with Healios. We expect our future contract revenue 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 by $0.2 million in the year ended December 31, 2017 compared to the year ended December 31, 2016, 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 $27.8 million for the year ended December 31, 2017 from $24.8 million for the year ended December 31, 2016. In 2017, approximately $4.7 million was expensed (of which $3.2 million was non-cash) related to a settlement and license agreement with Garnet to resolve a long-standing intellectual property dispute. After factoring in the one-time charge for Garnet, the decrease in research and development expenses year-over-year of $1.7 million related primarily to reduced spending on research supplies of $0.9 million and sponsored research of $0.5 million. Based on our clinical development, manufacturing and process development planning, we expect our 2018 annual research and development expenses to be higher compared to 2017, 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 $8.5 million in 2017 from $7.8 million in 2016. The $0.7 million increase was due primarily to increases in personnel costs and legal and professional services. We expect our general and administrative expenses to increase in 2018 due to the implementation of a new enterprise resource planning system.

Depreciation. Depreciation expense increased to $0.7 million in 2017 from $0.4 million in 2016 due to equipment purchases and assets placed in service following 2016 flood repairs.

Income (Expense) from Change in Fair Value of Warrants. Income of $0.7 million and expense of $0.6 million was recognized during the years ended December 31, 2017 and 2016, 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. As of March 2017, we no longer had any warrants outstanding.

Other Income (Expense), net. Other income (expense), net, for the years ended December 31, 2017 and 2016 remained relatively consistent and was comprised of interest income and expense, refundable foreign tax credits and foreign currency gains and losses.

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. 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.

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.

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 following 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.

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, refundable foreign tax credits and foreign currency gains and losses.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances. At December 31, 2017, we had $29.3 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 $350.6 million at December 31, 2017. 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 all of our sources of capital to develop our technologies, to discover and develop therapeutic product candidates, develop business collaborations and to acquire certain technologies and assets.

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.

We have had an equity purchase arrangement in place with Aspire Capital since 2011, through two-to-three year equity facilities, each with similar terms. The most current facility with Aspire Capital was entered into in February 2018 and included Aspire's commitment to purchase up to an aggregate of $100.0 million of shares of our common stock over a new three-year period, and an investment in us of $1.0 million at $2.00 per share of common stock. Furthermore, the prior facility that was entered into in December 2015 has approximately 2.0 million shares that remain available to us for issuance. During the years ended December 31, 2017 and 2016, we sold 9,400,000 and 2,191,418 shares, respectively, to Aspire Capital at average prices of $1.75 and $1.84 per share, respectively. As of December 31, 2017, we received proceeds of approximately $45.2 million in aggregate under the Aspire equity facility since its inception in 2011. In January and February 2018, we generated an additional $5.5 million in proceeds from the use of the equity purchase arrangement, including a $1.0 million investment by Aspire Capital in our capital stock in connection with entering into the February 2018 facility.

During the year ended December 31, 2017 and 2016, we received proceeds of approximately $1.9 million and $0.2 million, respectively, from the exercise of warrants. All of our previously outstanding warrants were either exercised prior to expiration or expired in March 2017, and we no longer have any warrants outstanding.

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 receive additional success-based development, regulatory approval and sales milestones of $225 million in aggregate, and tiered royalties on product sales that start in the low double digits and increase incrementally into the high teens depending on net sales levels. Additionally, we receive payments for product supplied to Healios under a manufacturing supply agreement, which is initially focused on clinical product supply, and in 2017, we agreed to a cost-sharing arrangement with Healios for clinical product for its TREASURE trial in Japan that may impact the amount of proceeds we receive from future milestones. We began receiving cost-sharing proceeds late in 2017. Under the manufacturing supply agreement, 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 addition, in September 2017, we entered into a services agreement with Healios, in which Healios provides financial support to establish a contract manufacturer in Japan to produce product for Healios. The services under this arrangement commenced in the fourth quarter of 2017.

In connection with the March 2018 LOI, we would be entitled to receive payments of $35 million ($10 million of which is guaranteed to be paid to us), as well as additional possible payments, including milestones and royalties. If the expansion agreements are entered into and, thereafter, Healios elects to exercise its option for the license in China, Healios would pay us license fees, milestone payments and escalating royalties or profit-sharing for each indication in China.

Also in March 2018, Healios purchased 12,000,000 shares of our common stock and a warrant to purchase up to an additional 20,000,000 shares of common stock for $21,100,000, or approximately $1.76 per share. The warrant does not become effective until the expansion agreements are effective, has a term that expires in September 2020 (subject to a potential nine-month extension), includes both fixed and floating exercise price mechanisms, and is capped such that in no event will Healios own more than 19.9% of our common stock. We may receive additional proceeds from the exercise of the warrant over its term, although there can be no assurances that Healios will exercise the warrant.

Under the terms of our RTI agreement, we are eligible to receive $34.5 million in remaining cash payments upon the successful achievement of certain commercial milestones, after the first commercial milestone payment of $1.0 million was achieved in 2017, though there can be no assurances that further such milestones will be achieved. 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 and in the fourth quarter of 2017, a second commercial milestone was achieved, resulting in an increase in the rate of royalties we receive on product sales by RTI, although there can be no assurances that further such milestones resulting in increased royalty rates will be achieved

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 no payments were received during 2017 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, 2017, we have paid no royalties to the University of Minnesota and have paid sublicense fees from time-to-time in connection with our collaborations.

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, 2017, we had available cash and cash equivalents of $29.3 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, 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 $24.0 million, $10.9 million and $13.8 million in 2017, 2016 and 2015, 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 $0.3 million, $1.1 million and $0.1 million in 2017, 2016 and 2015, 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 increase in 2018 compared to 2017.

Financing activities provided net cash of $38.9 million in 2017, $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 shares of common stock retained for withholding taxes on share-based awards.

Our contractual payment obligations as of December 31, 2017 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	**$ 460,000**	**$ 385,000**	**$ 75,000**	$ —	$ —
License fee related to intellectual property	**1,900,000**	**1,900,000**	—	—	—
	$2,360,000	**$ 2,285,000**	**$ 75,000**	**$ —**	**$ —**

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 2019, and we intend to renew the agreement. 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 2018 and includes options to renew annually through July 2022, and the annual rent of approximately $185,000 is subject to adjustments based on an inflationary index. Our total rent expense for all properties was $477,000 in 2017.

In October 2017, we entered into an agreement to settle longstanding intellectual property disagreements with a third party. As part of the agreement, we were granted a worldwide, non-exclusive license, with the right to sublicense, to the other party's patents and applications that were at the core of the intellectual property dispute, for use related to the treatment or prevention of disease or conditions using cells. In return, we agreed not to enforce our intellectual property rights against the party with respect to certain patent claims, nor to further challenge the patentability or validity of certain applications or patents. In connection with the license and settlement agreement, we paid $500,000 and issued 1,000,000 shares of our common stock upon execution of the agreement, and we will pay an additional $250,000 over each of the next four quarters. Additionally, we will issue 500,000 shares of common stock upon issuance of a patent from the party's patent applications at the core of the dispute. There will be no royalty, milestone or other payments due to the third party associated with the development and commercialization of our cell therapy products.

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 polices 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 the arrangements had standalone value and objective and reliable evidence of fair value, and if so, the arrangements 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.

Refer to Note B to the consolidated financial statements in Item 8. for a discussion of the expected impact of our adoption of FASB's ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* on January 1, 2018.

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. We recognize the impact of forfeitures as they occur.

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.

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, including the MASTERS-2 Phase 3 clinical trial and the Healios TREASURE clinical trial in Japan;
- 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, including the success of our collaboration with Healios;
- 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, 2017, we had no investments.

We have entered into loan arrangements with financial institutions when needed and when available to us. At December 31, 2017, we had no borrowings outstanding.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Athersys, Inc.

Consolidated Financial Statements

Years Ended December 31, 2017, 2016 and 2015

Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
Athersys, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Athersys, Inc. and subsidiaries (the Company) as of December 31, 2017 and 2016, 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, 2017, and the related notes and financial statement schedule listed in the index at Item 15(a) (2) (collectively referred as the "consolidated financial statements"). In our opinion the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, 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 15, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1998.

Cleveland, Ohio
March 15, 2018

Report of Independent Registered Public Accounting Firm

To Board of Directors and Stockholders of
Athersys, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Athersys, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2017, 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). In our opinion, Athersys, Inc. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2017 and December 31, 2016, 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, 2017, and the related notes and financial statement schedule listed in the Index at Item 15(a)(2) and our report dated March 15, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, 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.

Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ Ernst & Young LLP

Cleveland, Ohio
March 15, 2018

Athersys, Inc.

Consolidated Balance Sheets

(In Thousands, Except Share and Per Share Amounts)

	December 31,	
	2017	**2016**
Assets		
Current assets:		
Cash and cash equivalents	**$ 29,316**	$ 14,753
Accounts receivable	**739**	598
Prepaid expenses and other	**1,135**	929
Total current assets	**31,190**	16,280
Equipment, net	**2,206**	2,605
Other	**197**	175
Total assets	**$ 33,593**	$ 19,060
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 4,469**	$ 4,761
Accrued compensation and related benefits	**1,065**	1,190
Accrued clinical trial costs	**1,453**	389
Accrued expenses	**425**	535
Accrued license fee expense	**1,900**	—
Deferred revenue	**771**	—
Total current liabilities	**10,083**	6,875
Advance from customer	**134**	—
Warrant liabilities	**—**	1,004
Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at December 31, 2017 and 2016	**—**	—
Common stock, $0.001 par value; 300,000,000 and 150,000,000 shares authorized at December 31, 2017 and 2016, respectively; 122,077,453 and 86,629,302 shares issued and outstanding at December 31, 2017 and 2016, respectively	**122**	87
Additional paid-in capital	**373,884**	329,373
Accumulated deficit	**(350,630)**	(318,279)
Total stockholders' equity	**23,376**	11,181
Total liabilities and stockholders' equity	**$ 33,593**	$ 19,060

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In Thousands, Except Share and Per Share Amounts)

	Year Ended December 31,		
	2017	2016	2015
Revenues			
Contract revenue	**$ 2,843**	$ 16,238	$ 10,298
Grant revenue	**865**	1,109	1,650
Total revenues	**3,708**	17,347	11,948
Costs and expenses			
Research and development (including stock compensation expense of $1,232, $1,192 and $1,277 in 2017, 2016 and 2015, respectively)	**27,841**	24,838	21,316
General and administrative (including stock compensation expense of $1,812, $1,676 and $1,652 in 2017, 2016 and 2015, respectively)	**8,466**	7,835	7,536
Depreciation	**684**	382	267
Total costs and expenses	**36,991**	33,055	29,119
Gain from insurance proceeds, net	**—**	682	—
Loss from operations	**(33,283)**	(15,026)	(17,171)
Income (expense) from change in fair value of warrants, net	**728**	(557)	772
Other income (expense), net	**314**	209	(61)
Loss before income taxes	**(32,241)**	(15,374)	(16,460)
Income tax benefit	**—**	37	38
Net loss and comprehensive loss	**$ (32,241)**	$ (15,337)	$ (16,422)
Net loss per common share, basic	**$ (0.29)**	$ (0.18)	$ (0.20)
Weighted average shares outstanding, basic	**112,053,369**	84,715,471	82,143,610
Net loss per common share, diluted	**$ (0.29)**	$ (0.18)	$ (0.20)
Weighted average shares outstanding, diluted	**112,053,369**	84,715,471	82,851,091

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Stockholders' Equity

(In Thousands, Except Share Amounts)

	Preferred Stock		Common Stock		Additional		Total
	Number of Shares	Stated Value	Number of Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity
Balance at January 1, 2015	—	$ —	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 and warrants, 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
Cumulative effect of accounting change						**(110)**	**(110)**
Stock-based compensation	**—**	**—**	**—**	**—**	**3,154**	—	**3,154**
Issuance of common stock from warrant exercises	—	—	**1,843,363**	**2**	**1,860**	—	**1,862**
Issuance of common stock, net of issuance costs	**—**	**—**	**33,172,300**	**33**	**39,780**	**—**	**39,813**
Issuance of common stock under equity compensation plans	**—**	**—**	**432,488**	—	**(283)**	—	**(283)**
Net and comprehensive loss	**—**	**—**	**—**	**—**	**—**	**(32,241)**	**(32,241)**
Balance at December 31, 2017	**—**	**$ —**	**122,077,453**	**$ 122**	**$ 373,884**	**$ (350,630)**	**$ 23,376**

See accompanying notes.

Athersys, Inc.

Consolidated Statements of Cash Flows

(In Thousands)

	Year Ended December 31,		
	2017	**2016**	**2015**
Operating activities			
Net loss	**$(32,241)**	$(15,337)	$(16,422)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	**684**	382	267
Gain from forgiveness of note payable	**—**	(190)	—
Stock-based compensation	**3,044**	2,868	2,929
Other	**(22)**	2	23
Stock – based patent license and settlement expense	**3,150**	—	—
Gain from insurance proceeds, net	**—**	(682)	—
Change in fair value of warrant liabilities	**(728)**	557	(772)
Changes in operating assets and liabilities:			
Accounts receivable	**(141)**	(237)	333
Prepaid expenses and other	**(206)**	(462)	4
Accounts payable and accrued expenses	**1,537**	2,413	(296)
Advance from customer	**134**	—	—
Deferred revenue	**771**	(245)	170
Net cash used in operating activities	**(24,018)**	(10,931)	(13,764)
Investing activities			
Purchase of available-for-sale securities	**—**	(16,343)	—
Sales of available-for-sale securities	**—**	16,305	—
Proceeds from insurance	**—**	682	—
Purchases of equipment	**(285)**	(1,711)	(132)
Net cash used in investing activities	**(285)**	(1,067)	(132)
Financing activities			
Proceeds from issuance of common stock, net	**37,287**	4,028	10,310
Proceeds from exercise of warrants	**1,862**	163	976
Shares retained for withholding tax payments on stock-based awards	**(283)**	(467)	(490)
Net cash provided by financing activities	**38,866**	3,724	10,796
Increase (decrease) in cash and cash equivalents	**14,563**	(8,274)	(3,100)
Cash and cash equivalents at beginning of year	**14,753**	23,027	26,127
Cash and cash equivalents at end of year	**$ 29,316**	$ 14,753	$ 23,027

See accompanying notes.

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 of research and later-stage product development activities.

We incurred losses since our inception in 1995 and had an accumulated deficit of $350.6 million at December 31, 2017. 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, 2017, we had available cash and cash equivalents of $29.3 million, and we believe that these funds, used to execute 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 license fees and milestones, the sale of equity securities from time to time including through our equity purchase agreement, grant-funding opportunities, deferring certain discretionary costs and staging certain development costs, as needed.

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, 2017, 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 included $1.0 million and $0.6 million in 2017 and 2016, respectively, from these collaborations related to 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. We began receiving in 2014 tiered royalties from RTI 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 in the fourth quarter of 2017, the royalty rate increased into the low double-digits based on RTI's achievement of a second commercial milestone. 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.

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. 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. At December 31, 2017, we had no available-for-sale securities, and realized gains and losses for each of the three years in the period ended December 31, 2017 on available-for-sale securities were insignificant and are 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, 2017. We may also pay sublicense fees from time-to-time in connection with our collaborations, of which $0.3 million and $0.2 million were paid in the years ended December 31, 2016 and 2015, respectively.

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 $0.7 million that was reported as a separate component of our loss from operations. Proceeds from insurance settlements, except for those directly related to investing or financing activities, were recognized as cash inflows from operating activities. 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. An additional $0.3 million of insurance proceeds were received in 2018.

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. Generally, warrants are classified as liabilities, as opposed to equity, if the agreement includes the potential for a cash settlement or an adjustment to the exercise price, and warrant liabilities are recorded at their fair values at each balance sheet date. 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, 2017, the majority of our accounts receivable are due from granting authorities and two collaborators. 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.

We recognize income tax benefits and deficiencies as income tax expense or benefit in the income statement and the tax effects of exercised or vested awards are treated as discrete items in the reporting period in which they occur. We also recognize excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. Excess tax benefits are classified along with other income tax cash flows as an operating activity. In regards to forfeitures, we adopted ASU 2016-09 on January 1, 2017, electing to account for forfeitures when they occur.

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,		
	2017	2016	2015
Volatility	**71.2%**	70.3%	83.9%
Risk-free interest rate	**2.0%**	1.5%	2.1%
Expected life of option	**6.2 years**	6.2 years	6.1 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, 2017 and 2016. 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. Refer to Note H regarding recent tax reform.

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 in which we have outstanding warrant liabilities, we evaluate the income from such warrant liabilities and consider whether it results in a potentially dilutive effect to net loss per share. For the year ended December 31, 2015, 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, 2017, 2016 and 2015, in thousands, except per share data.

	Year ended December 31,		
	2017	2016	2015
Numerator:			
Net loss and comprehensive loss	**$ (32,241)**	$(15,337)	$(16,422)
Less: income from change in fair value of warrants	**—**	—	(332)
Net loss attributable to common stockholders used to calculate diluted net loss per share	**$ (32,241)**	$(15,337)	$(16,754)
Denominator:			
Weighted-average shares outstanding - Basic	**112,053**	84,715	82,144
Potentially dilutive common shares outstanding:			
Warrants	**—**	—	707
Weighted-average shares used to calculate diluted net loss per share	**112,053**	84,715	82,851
Basic – net loss per share	**$ (0.29)**	$ (0.18)	$ (0.20)
Dilutive – net loss per share	**$ (0.29)**	$ (0.18)	$ (0.20)

We have outstanding options, restricted stock units and previously outstanding warrants that were 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,		
	2017	2016	2015
Stock options	**8,919,113**	9,236,228	7,052,642
Restricted stock units	**1,648,986**	1,201,159	1,069,100
Warrants	**—**	1,893,527	2,810,000
	10,568,099	12,330,914	10,931,742

Recently Issued Accounting Standards

In March 2016, the FASB ("FASB") issued Accounting Standards Update ("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. We adopted this ASU on January 1, 2017, electing to account for forfeitures when they occur, and we recognized a cumulative effect adjustment to accumulated deficit on a modified-retrospective basis as of January 1, 2017 of approximately $0.1 million upon adoption.

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. We currently have operating leases for two facilities that will need to be evaluated under this new guidance.

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. The new standard is effective for annual and interim reporting periods beginning after December 15, 2017, and we did not elect to early adopt the standard in 2017.

We will adopt this guidance in the first quarter of 2018, utilizing the modified retrospective transition method only with respect to contracts that were not complete as of January 1, 2018. We evaluated all of our collaborative agreements on a contract-by-contract basis, identifying all of the performance obligations, including those that are contingent, and whether a contract had stand-alone value. Under the new standard, we are required to assess whether licenses granted under our collaboration and license agreements are distinct in the context of the agreement from other performance obligations and functional when granted. After considering the relative selling prices of the contract elements and the allocation of revenue, thereto, we expect to have a cumulative effect adjustment related to a corresponding contract asset, primarily since the revenue permitted to be recognized at inception was not limited to the cash proceeds received as of that time, which was a requirement of the previous guidance. We also concluded that the new guidance resulted in revisions to accounting for our arrangement with Healios K.K. ("Healios"), only, since our other collaborations had no remaining performance obligations and potential contingent receipts would be constrained.

We expect that license-related amounts, including upfront payments, exclusivity fees, additional disease indication fees, and development, regulatory and sales-based milestones will be recognized, generally, at a point in time when earned. Similarly, product supply revenue is expected to be recognized at a point in time while any service revenue will be recognized over time when earned.

Topic 606 does not contain guidance specific to milestone payments but rather, requires potential milestone payments to be considered in accordance with the overall model of Topic 606. As a result, revenues from contingent milestone payments may be recognized earlier under Topic 606 than under Topic 605, based on an assessment of the probability of achievement of the milestone and the likelihood of a significant reversal of such milestone revenue at each reporting date. This assessment may result in recognizing milestone revenue before the milestone event has been achieved. In addition, Topic 606 changes guidance regarding the accounting for variable consideration received from license arrangements, which may impact the estimation of, and determination of the timing of, our related revenue recognition.

As of December 31, 2017, we have substantially completed our planning to apply the necessary changes to accounting processes, procedures, systems and internal controls, and we plan to finalize our transition adjustment under Topic 606 in the first quarter of 2018.

C. Equipment

	December 31,	
Equipment consists of (in thousands):	**2017**	2016
Laboratory equipment	**$ 6,262**	$ 6,196
Office equipment and leasehold improvements	**3,039**	3,040
Process development equipment not yet in service	**363**	965
	9,664	10,201
Accumulated depreciation	**(7,458)**	(7,596)
	$ 2,206	$ 2,605

In 2017 and 2016, we disposed of approximately $0.8 million and $0.6 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.

At December 31, 2017, we had no financial assets or liabilities measured at fair value on a recurring basis. At December 31, 2016, we had warrant liabilities of $1.0 million that represented Level 3 liabilities under the hierarchy. In March 2017, these warrants were either exercised or expired, and we no longer have any outstanding warrants.

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 any outstanding warrant liabilities at fair value. The fair value is estimated using the expected volatility based on our historical volatility and is determined using probability weighted-average assumptions, when appropriate.

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, 2017
Balance January 1, 2017	$ 1,004
Settlements from exercise	(276)
Gain included in income from change in fair value of warrants	(728)
Balance December 31, 2017	**$ —**

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 2019, and we intend to renew our agreement. 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 2018 and includes options to renew annually through July 2022, with annual rent of approximately $185,000, subject to adjustments based on an inflationary index.

Aggregate rent expense was approximately $477,000, $465,000 and $467,000 in 2017, 2016 and 2015, respectively. The future annual minimum lease commitments at December 31, 2017 are approximately $385,000 for 2018 and $75,000 for 2019.

We paid no interest during the three years ended December 31, 2017.

E. Collaborative Arrangements and Revenue Recognition

Healios

In 2016, we entered into a license agreement ("Healios Agreement") with 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 Healios 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 ("ARDS") and another indication in the orthopedic area, and to include all indications for the "organ bud" program. Healios may exercise its option to expand the collaboration prior to certain milestone dates that are expected to occur within the next several years.

Under the terms of the Healios Agreement, we received a nonrefundable, up-front cash payment of $15 million from Healios. Healios is responsible for the costs of clinical development in Japan. Athersys is providing manufacturing services to Healios, currently comprising the supply of product for its clinical trial and preparations for commercial manufacturing, and we receive payments for product supplied to Healios. We also receive financial support from Healios for services we perform to establish a contract manufacturer in Japan to produce product for Healios. The costs of the services are reimbursed by Healios at our actual cost, without mark-up.

For the ischemic stroke indication, we may also receive additional success-based development, regulatory approval and sales milestones, which 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.

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 a cash payment of $10 million at the time of exercise and 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 certain dates in the future.

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, and for deliverables with standalone value, our policy is to 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 at the inception of the arrangement, we concluded that the license had stand-alone value and would be treated as a separate unit of accounting, noting that there was no general right of return associated with the license. Furthermore, the preclinical and clinical manufacturing services and certain near-term regulatory advisory services provided to Healios were also 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 at inception, we allocated $15 million of the proceeds received to the license, which represents the amount of consideration that is allocable at inception pursuant to the relative selling price and was not contingent upon delivery of additional items under the Healios Agreement. The license was delivered and the proceeds allocated to it were recognized as revenue in 2016. Amounts received under the Healios Agreement are included within contract revenues in the consolidated statement of operations and comprehensive loss.

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. Furthermore, 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 or modifications to the deliverables under the arrangement, we will reevaluate the allocation of consideration to the remaining undelivered items, including the estimated selling prices, with any changes in estimates accounted for on a prospective basis.

In January 2017, we signed a clinical trial supply agreement for the manufacturing of investigational product for Healios for its Japan clinical study, the terms of which were consistent with the Healios Agreement. The clinical trial supply agreement was amended in July 2017 to clarify a cost-sharing arrangement associated with our supply of clinical materials. The proceeds from Healios that relate specifically to the cost-sharing arrangement may result in a reduction in the proceeds we receive from Healios upon the achievement of two future milestones, and an increase to a later-stage commercial milestone. Of the aggregate $225 million of potential proceeds from success-based development, regulatory approval and sales milestones, the maximum net decrease related to this cost-sharing arrangement amounts to less than 3% of the aggregate milestones. While the amendment to the supply agreement resulted in a revision to the terms associated with the product supply under the Healios Agreement, namely the cost of product supply, the revision did not affect any of the deliverables under the overall arrangement. Therefore, the allocation of revenue as of the inception of the arrangement to the undelivered items was unchanged, and the cost-sharing proceeds received are recognized on the balance sheet as a non-current advance from customer until the related milestone is achieved or such amounts are repaid to Healios at our election, at which time, the culmination of the earnings process will be complete and revenue will be recognized.

In September 2017, we entered into a services agreement with Healios, in which Healios provides financial support to establish a contract manufacturer in Japan to produce product for Healios, and services began in the fourth quarter of 2017. We evaluated this amendment as a combined agreement along with the Healios Agreement due to its connection to the license and the product supply under the Healios Agreement. The costs of the services are reimbursed by Healios at our actual cost, without mark-up. Given that Healios will benefit from the services as the services are performed, which is the intended purpose of the arrangement, we concluded that the services had stand-alone value at the time of the amendment and are treated as a separate unit of accounting, noting also that there was no general right of return. We reevaluated the estimated selling prices and transaction proceeds under the Healios arrangement since this service agreement resulted in a new deliverable, and allocated revenue to the remaining undelivered items. The revenue from the services are recognized as contract revenues as the services are performed.

Furthermore, in September 2017, we amended the Healios Agreement to confer to Healios a limited license to manufacture MultiStem in the event that we are acquired by a third party. Such amendment was evaluated as a combined agreement along with the Healios Agreement, noting that the amendment represented a contingent deliverable and, therefore, had no impact on the allocation of revenue to the remaining undelivered items.

Refer to Note B for a discussion of the expected impact of our adoption of Topic 606 on January 1, 2018.

Refer to Note J for disclosure of subequent events related to our Healios collaboration.

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.

Other

Under our agreement with RTI to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market, we are eligible to receive up to $34.5 million in remaining cash payments upon the successful achievement of certain commercial milestones, after the first commercial milestone payment of $1.0 million was received in 2017. 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, and in the fourth quarter of 2017, our royalty rate increased as a result of reaching a milestone for product sales.

In January 2017, we received an option fee related to an agreement 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 the animal health area. The option fee is recorded as deferred revenue at December 31, 2017 since the performance obligation of granting a license has not occurred. If the option is exercised, we will include the option fee in the overall consideration for the license arrangement, to be evaluated at that time. If the option is not exercised, the option fee will be recognized as revenue at that time since there will be no more performance obligations. The evaluation of our technology for this application is currently ongoing.

F. Capitalization and Warrant Liability

Capitalization

At December 31, 2017, we had 300 million (150 million at December 31, 2016) shares of common stock and 10.0 million shares of undesignated preferred stock authorized. In June 2017, our stockholders approved an amendment to our certificate of incorporation to increase the number of authorized shares of common stock to 300 million. No shares of preferred stock have been issued as of December 31, 2017. Other than the change to the number of authorized shares of common stock, there were no changes to the terms of our common stock.

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.

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

	December 31	
	2017	**2016**
Stock-based compensation plans	**16,952,125**	17,940,618
Warrants to purchase common stock	**—**	1,893,527
Shares issuable upon patent milestone	**500,000**	—
	17,452,125	19,834,145

The outstanding warrants as of December 31, 2016 to purchase shares of common stock had an exercise price of $1.01 per share and expired or were exercised by March 2017. Proceeds from warrant exercises were $1.9 million, $0.2 million and $1.0 million in 2017, 2016 and 2015, respectively.

Aspire Capital

We have had an equity purchase arrangement in place with Aspire Capital Fund LLC ("Aspire Capital") since 2011, through two-to-three year equity facility agreements, each with similar terms. The most recent agreement with Aspire Capital was entered into in February 2018 and includes Aspire Capital's commitment to purchase up to an aggregate of $100.0 million of shares of our common stock over a three-year period. The terms of the 2018 equity facility are similar to the previous arrangements, and we issued 450,000 shares of our common stock to Aspire Capital as a commitment fee in February 2018 and filed a registration statement for the resale of 24,700,000 shares of common stock in connection with the new equity facility. Also in connection with the new equity facility, in February 2018, Aspire Capital invested $1.0 million in us at $2.00 per share of common stock. During the years ended December 31, 2017, 2016 and 2015, we sold 9,400,000, 2,191,418, and 4,023,719 shares, respectively, to Aspire Capital at average prices of $1.75, $1.84 and $2.58 per share, respectively. As of December 31, 2017, we have received proceeds of approximately $45.2 million in aggregate under the Aspire equity purchase agreements since its inception in 2011. In January and February 2018, we generated $4.5 million of proceeds from the use of our 2015 agreement with Aspire Capital, which was not terminated upon entering into the 2018 agreement, and as of February 28, 2018, we had approximately 2.0 million shares remaining to sell to Aspire Capital under the 2015 agreement.

License Agreement and Settlement

In October 2017, we entered into an agreement to settle longstanding intellectual property disagreements with a third party. As part of the agreement, we were granted a worldwide, non-exclusive license, with the right to sublicense, to the other party's patents and applications that were at the core of the intellectual property dispute, for use related to the treatment or prevention of disease or conditions using cells. In return, we agreed not to enforce our intellectual property rights against the party with respect to certain patent claims, nor to further challenge the patentability or validity of certain applications or patents. In connection with the license and settlement agreement, we paid $500,000 and issued 1,000,000 shares of our common stock with a fair value of $2.3 million upon execution of the agreement, and we will pay an additional $250,000 over each of the next four quarters. Additionally, we will issue 500,000 shares of common stock upon the issuance of a patent from the party's patent applications at the core of the dispute, which we deem to be probable. There will be no royalty, milestone or other payments due to the third party associated with the development and commercialization of our cell therapy products. We have included the $1.0 million cash obligation and the contingent obligation to issue 500,000 shares of common stock, at fair value of $0.9 million at December 31, 2017, in accrued license fee expense on the consolidated balance sheets.

G. Stock-Based Compensation

We have an incentive plan that authorized an aggregate of 20,035,000 shares of common stock for awards to employees, directors and consultants. The equity incentive plan authorizes 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. As of December 31, 2017, a total of 4,266,556 shares (including 232,622 shares related to an expired incentive plan) of common stock have been issued under our equity incentive plan.

As of December 31, 2017, a total of 6,384,026 shares were available for issuance under our equity compensation plan, and stock-based awards to purchase 10,568,099 shares (including 951,059 shares related to an expired incentive plan) of common stock were outstanding. We recognized $3.0 million, $2.9 million and $2.9 million of stock-based compensation expense in 2017, 2016 and 2015, respectively.

Stock Options

The weighted average fair value of options granted in 2017, 2016 and 2015 was $0.95, $1.35 and $0.94 per share, respectively. The total fair value of options vested during 2017, 2016 and 2015 was $2.0 million, $1.7 million and $1.2 million, respectively. At December 31, 2017, total unrecognized estimated compensation cost related to unvested stock options was approximately $4.5 million, which is expected to be recognized by the end of 2021 using the straight-line method. The weighted average contractual life of unvested options at December 31, 2017 was 8.86 years. The aggregate intrinsic value of fully vested option shares and option shares expected to vest as of December 31, 2017 was $1.8 million.

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

	Number of Options	Weighted Average Exercise Price
Outstanding January 1, 2015	6,383,457	$ 3.31
Granted	1,215,296	1.31
Exercised	(32,439)	1.60
Forfeited / Terminated / 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
Granted	2,596,480	1.47
Exercised	(136,056)	1.50
Forfeited / Expired	(2,777,539)	4.76
Outstanding December 31, 2017	**8,919,113**	**$ 1.78**
Vested during 2017	**1,666,915**	**$ 1.78**
Vested and exercisable at December 31, 2017	**4,803,470**	**$ 1.86**

	December 31, 2017					
	Options Outstanding			Options Vested and Exercisable		
Exercise Price	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 – 1.96	6,326,094	7.73	$ 1.53	3,516,361	6.69	$ 1.58
$2.09 – 3.84	2.423.519	8.04	$ 2.24	1,117,609	7.53	$ 2.30
$4.00 – 5.28	169,500	1.09	$ 4.69	169,500	1.09	$ 4.69
	8,919,113			**4,803,470**		

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, 2015	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

	Number of Restricted Stock Units	Weighted Average Fair Value
Outstanding December 31, 2016	1,201,159	1.92
Granted	1,054,720	1.46
Vested-common stock issued	(571,118)	1.75
Forfeited / Expired	(35,775)	1.82
Outstanding December 31, 2017	**1,648,986**	**$ 1.69**
Vested/Issued cumulative at December 31, 2017	**3,828,441**	**$ 1.71**

The total fair value of restricted stock units vested during 2017, 2016 and 2015 was $1.0 million, $1.3 million and $1.8 million, respectively. At December 31, 2017, total unrecognized estimated compensation cost related to unvested restricted stock units was approximately $2.7 million, which is expected to be recognized by the end of 2021 using the straight-line method.

H. Income Taxes

At December 31, 2017, we had U.S. federal net operating loss and research and development tax credit carryforwards of approximately $136.6 million and $7.3 million, 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 2021 and 2037. We also had foreign net operating loss carryforwards of approximately $19.9 million. Such foreign net operating loss carryforwards do not expire. We also had state and city net operating loss carryforwards aggregating approximately $69.4 million. Such operating losses may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2018 and 2037.

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, (the "IRC") as a result of our equity offering that occurred in October 2012. We generated U.S. federal net operating loss carryforwards of $99.9 million, research and development tax credits of $7.3 million, and state and local net operating loss carryforwards of $69.4 million 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	
	2017	2016
Statutory Federal income tax rate	**34.0%**	34.0%
State income taxes - net of Federal tax benefit	**0.8%**	0.8%
Other permanent differences	**(5.5%)**	(8.1%)
Valuation allowances	**24.1%**	(37.0%)
Federal rate change	**(57.9%)**	0.0%
Research and development - U.S.	**4.5%**	10.3%
Research and development - Foreign	**0.0%**	0.2%
Effective tax rate for the year	**0.0%**	0.2%

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

	December 31,	
	2017	2016
Net operating loss carryforwards	**$35,409**	$44,929
Research and development credit carryforwards	**7,301**	6,017
Compensation expense	**652**	2,735
Other	**1,467**	1,266
Total deferred tax assets	**44,829**	54,947

	December 31,	
	2017	2016
Valuation allowance for deferred tax assets	**(44,829)**	(54,772)
Net deferred tax assets	**$ —**	$ 175

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, 2017.

On December 22, 2017, the U.S. federal government enacted legislation commonly referred to as the "Tax Cuts and Jobs Act" (the "TCJA"). The TCJA makes widespread changes to the IRC, including, among other items, a reduction in the federal corporate tax rate from 35% to 21%, effective January 1, 2018. The carrying value of our deferred tax assets and liabilities is also determined by the enacted U.S. corporate income tax rate. Consequently, any changes in the U.S. corporate income tax rate will impact the carrying value of our deferred tax assets and liabilities. Under the new corporate income tax rate of 21%, deferred income tax assets, net, have provisionally decreased by $18.7 million and the valuation allowance has had a corresponding decrease. The Deemed Repatriation Transition Tax (Transition Tax) is a tax on previously untaxed accumulated and current earnings and profit (E&P) of certain of our foreign subsidiaries. To determine the amount of Transition Tax, a company must determine, in addition to other factors, the amount of post-1986 E&P of the relevant foreign subsidiaries as well as the amount of non-U.S. income tax paid on such earnings. The Company believes it has an overall foreign E&P deficit and accordingly has not recorded any provisional Transition Tax obligation as of December 31, 2017. However, the Company is continuing to gather additional information to finalize its Transition Tax liability. We determined that the provisional calculations will be finalized after the underlying timing differences and foreign earnings and profits are finalized with our 2017 federal tax return filing. Furthermore, we are still analyzing certain aspects of the TCJA and refining our calculations which could potentially affect the measurement of these balances or potentially give rise to new or additional deferred tax amounts. We will consider additional guidance from the U.S. Treasury Department, IRS or other standard-setting bodies. Further adjustments, if any, will be recorded by us during the measurement period in 2018, as permitted by SEC Staff Accounting Bulletin 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act*.

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 $0.3 million in each of 2017, 2016 and 2015.

J. Subsequent and Other Events

In March 2018, we entered into a binding letter of intent (the "LOI") with Healios to significantly expand Healios' license to develop MultiStem products. Under the terms of the LOI, we and Healios will work to execute the agreements necessary to expand the existing collaboration by April 30, 2018. If the expansion is consummated, Healios would, among other things, (i) expand its license in Japan to include ARDS, including idiopathic pulmonary fibrosis ("ARDS Field"), trauma and use of MultiStem for organ buds for all organ diseases, (ii) obtain a worldwide exclusive license for use of MultiStem product to treat certain ophthalmological indications, and (iii) obtain an exclusive option to a license to develop and commercialize MultiStem products for ischemic stroke, the ARDS Field and trauma in China. In exchange, we would be entitled to receive payments of $35 million ($10 million of which is guaranteed to be paid to us), as well as additional possible payments, including milestones and royalties. If the expansion agreements are entered into and, thereafter, Healios elects to exercise its option for the license in China, Healios would pay us license fees, milestone payments and escalating royalties or profit-sharing for each indication in China.

Also in March 2018, Healios purchased 12,000,000 shares of our common stock and a warrant to purchase up to an additional 20,000,000 shares of common stock for $21,100,000, or approximately $1.76 per share. The warrant does not become effective until the expansion agreements are effective, has a term that expires in September 2020 (subject to a potential nine-month extension), includes both fixed and floating exercise price mechanisms, and is capped such that in no event will Healios own more than 19.9% of our common stock. We and Healios have entered into an investor rights agreement that governs certain rights and obligations relating to Healios' ownership of our common stock, including rights regarding Board of Director nominees.

K. Quarterly Financial Data (unaudited)

The following table presents quarterly data for the years ended December 31, 2017 and 2016, in thousands, except per share data:

	2017				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
Revenues	**$ 1,470**	**$ 669**	**$ 399**	**$ 1,170**	**$ 3,708**
Net loss	**$(5,631)**	**$(6,267)**	**$(7,243)**	**$(13,100)**	**$(32,241)**
Basic net loss per common share	**$ (0.06)**	**$ (0.06)**	**$ (0.06)**	**$ (0.11)**	**$ (0.29)**
Diluted net loss per common share	**$ (0.06)**	**$ (0.06)**	**$ (0.06)**	**$ (0.11)**	**$ (0.29)**

	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)

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, 2017, 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, 2017. The effectiveness of our internal control over financial reporting as of December 31, 2017 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 2017, 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 4, 2018, 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, 2018 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, 2018 through December 31, 2018. 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.

Title	Target Bonus	Weighting on Corporate Goals
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 10.33 and is hereby incorporated herein by reference thereto.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to the Proxy Statement with respect to the 2018 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the Proxy Statement with respect to the 2018 Annual Meeting of Stockholders.

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, 2017, unless otherwise indicated.

Plan Category	Number of securities to be issued upon exercise of outstanding awards (a) (1)	Weighted-average exercise price of outstanding awards (b) (2)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) (1)
Equity compensation plan approved by security holders	9,617,040	$ 1.81	6,384,026
Equity compensation plan not approved by security holders (3)	951,059	$ 1.57	—
Total	10,568,009		6,384,026

(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 $1.78 and the weighted average remaining term is 7.69 years.
(3) The shares of common stock included in this plan category are issuable pursuant to outstanding awards under the Athersys, Inc. Equity Incentive Compensation Plan. This plan expired on June 8, 2017, therefore no new awards can be issued under this plan.

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

The information required by this item is incorporated by reference to the Proxy Statement with respect to the 2018 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to the Proxy Statement with respect to the 2018 Annual Meeting of Stockholders.

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, 2017 and 2016

Consolidated Statements of Operations and Comprehensive Loss for each of the years ended December 31, 2017, 2016 and 2015

Consolidated Statements of Stockholders' Equity for each of the years ended December 31, 2017, 2016 and 2015

Consolidated Statements of Cash Flow for each of the years ended December 31, 2017, 2016 and 2015

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, 2017				
Deducted from asset accounts:				
Allowance for doubtful accounts- note receivable	$ 376	$ —	$ (376)	$ 0(A)
Tax valuation allowances	$ 54,772	$ —	$ (9,943)	$ 44,829(B)
Total 2017	**$ 55,148**	**$ —**	**$ (10,319)**	**$ 44,829**
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(B)
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(B)
Total 2015	**$ 42,204**	**$ 7,080**	**$ —**	**$ 49,284**

(A) – Reserve on note receivable that was fully-reserved. We wrote-off the note in 2017.
(B) – Substantially all of our deferred tax assets are offset by valuation allowances.

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 20, 2013 (incorporated herein by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on August 13, 2013)
3.2	Certificate of Amendment to Certificate of Incorporation of Athersys, Inc., as amended as of June 7, 2017 (incorporated herein by reference to Exhibit 3.1 to the registrant's Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on August 9, 2017)
3.3	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)
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)
10.7†	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)
10.8†	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)
10.9†	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)

10.10†	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)
10.11†	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)
10.12†	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)
10.13†	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)
10.14†	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)
10.15†	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)
10.16†	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)
10.17†	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)
110.18†	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)
10.19†	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)
10.20†	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)
10.21†	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)
10.22†	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. 001-33876) filed with the Commission on June 20, 2013)

10.23*	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)
10.24	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)
10.25*	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)
10.26†	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)
10.27†	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)
10.28†	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)
10.29†	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)
10.30†	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)
10.31†	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)
10.32	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)
10.33†	Summary of Athersys, Inc. 2017 Cash Bonus Incentive Plan (incorporated herein by reference to Exhibit 10.42 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2016 (Commission No. 001-33876) filed with the Commission on March 10, 2017)
10.34	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)
10.35	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)
10.36†	Summary of Athersys, Inc. 2018 Cash Bonus Incentive Plan
10.37	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)

10.38	Common Stock Purchase Agreement, dated as of February 1, 2018, by and between Athersys, Inc. and Aspire Capital Fund, LLC (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 February 1, 2018).
10.39	Registration Rights Agreement, dated as of February 1, 2018, 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 February 1, 2018).
10.40	First Amendment to License Agreement, dated as of July 21, 2017, by and between ABT Holding Company and Healios K.K. (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, 2017)
10.41	Second Amendment to License Agreement, dated as of September 19, 2017, by and between ABT Holding Company and Healios K.K. (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 November 8, 2017)
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 15, 2018.

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.

Signature	Title	Date
/s/ Gil Van Bokkelen Gil Van Bokkelen	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 15, 2018
/s/ Laura K. Campbell Laura K. Campbell	Senior Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)	March 15, 2018
* John J. Harrington	Executive Vice President, Chief Scientific Officer and Director	March 15, 2018
* Lorin J. Randall	Director	March 15, 2018
* Jordan S. Davis	Director	March 15, 2018
* Jack L. Wyszomierski	Director	March 15, 2018
* Lee E. Babiss	Director	March 15, 2018
* Ismail Kola	Director	March 15, 2018

* 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 31.1

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 15, 2018

/s/ Gil Van Bokkelen

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

EXHIBIT 31.2

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 15, 2018

/s/ Laura K. Campbell
Laura K. Campbell
Senior Vice President of Finance

EXHIBIT 32.1

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, 2017, 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 15, 2018

/s/ Gil Van Bokkelen
Name: Gil Van Bokkelen
Title: Chairman and Chief Executive Officer

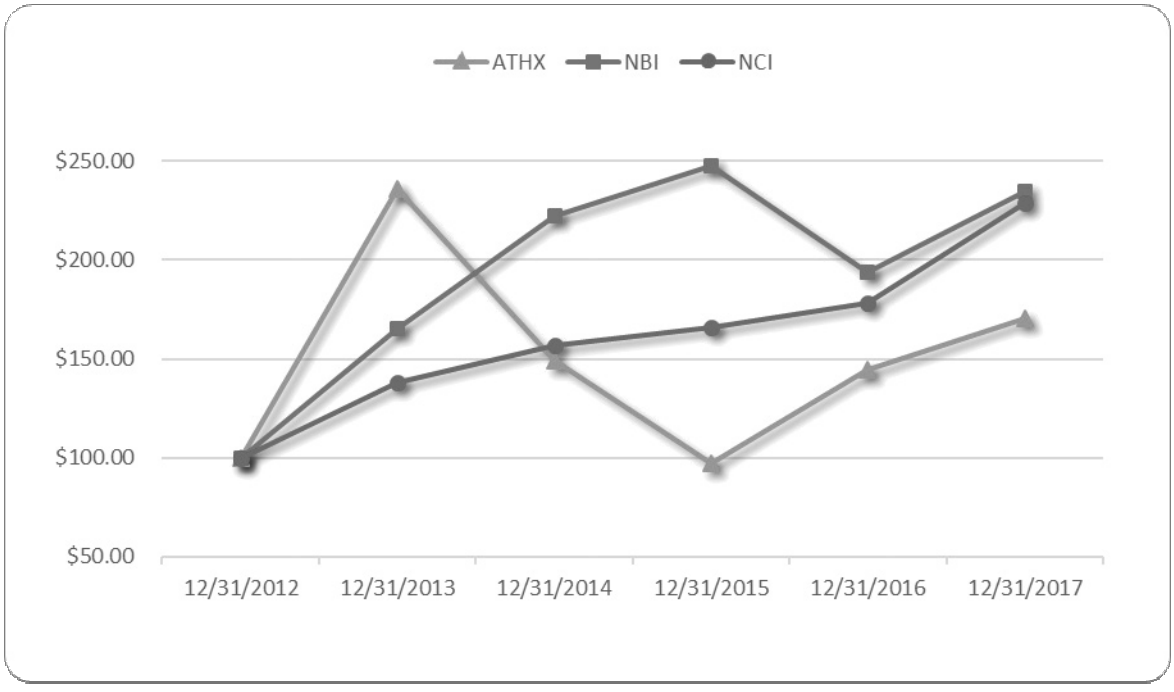
/s/ Laura K. Campbell
Name: Laura K. Campbell
Title: Senior Vice President of Finance

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.

Stock Performance Graph

Notwithstanding any statement to the contrary in any of our previous of previous or future filings with the Securities and Exchange Commission, the following information relating to the price performance of our common stock shall not be deemed "filed" with the Commission or "soliciting material" under the Securities Exchange Act of 1934 and shall not be incorporated by reference into any such filings.

The following graph shows a comparison from December 31, 2012 through December 31, 2017 of cumulative total return for the NASDAQ Composite Index (IXIC), our common stock (ATHX) and the NASDAQ Biotechnology Index (NBI). Data for the NCI and the NBI assumes reinvestment of dividends. We have never paid dividends on our common stock and have no present plans to do so.



These returns are based on historical results, assuming $100 was invested on December 31, 2012 in the NCI, NBI or our common stock and are not intended to suggest future performance.

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MANAGEMENT

Gil Van Bokkelen, Ph.D.
Chairman and Chief Executive Officer

William (B.J.) Lehmann, Jr., J.D.
President and Chief Operating Officer

John Harrington, Ph.D.
Chief Scientific Officer, Executive Vice President and Director

Laura Campbell, C.P.A.
Senior Vice President of Finance

Manal Morsy, M.D., Ph.D., MBA
Senior Vice President, Global Regulatory Affairs

Robert (Willie) Mays, Ph.D.
Vice President of Regenerative Medicine, Head of Neuroscience Programs

Anthony Ting, Ph.D.
Vice President of Regenerative Medicine, Head of Cardiopulmonary Programs

Rakesh Ramachandran, M.S.
Vice President, Information Technology and Communications

Raymond Starling, Ph.D.
Vice President, Clinical Development and Operations

MEDIA RELATIONS

Russo Partners, LLC
David Schull
T: (212) 845-4271
David.schull@russopartnersllc.com

BOARD OF DIRECTORS

Gil Van Bokkelen, Ph.D.
Chairman and Chief Executive Officer of Athersys, Inc. and Chairman of the Board of Governors of the National Center for Regenerative Medicine

Lee. E. Babiss, Ph.D.
Lead Director
Chief Executive Officer of Gotham Therapeutics Corp.

Jordan S. Davis
Managing Partner of Radius Ventures, LLC

John J. Harrington, Ph.D.
Chief Scientific Officer, Executive Vice President and Director of Athersys, Inc.

Ismail Kola, Ph.D.
Retired; former Executive Vice President of UCB S.A. and President and Chief Scientific Officer of UCB New Medicines

Lorin J. Randall
Independent financial consultant; former Senior Vice President and Chief Financial Officer of Eximias Pharmaceutical Corporation

Jack L. Wyszomierski
Retired; former Executive Vice President and Chief Financial Officer of VWR International, LLC

STOCKHOLDER INFORMATION

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Athersys, Inc.
3201 Carnegie Avenue
Cleveland, OH 44115-2634
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F: (216) 361-9495
www.athersys.com

Independent Auditors
Ernst & Young, LLP
Cleveland, OH 44114

Investor Relations
Karen Hunady
T: (216) 431-9900 ext. 511
khunady@athersys.com

Registrar and Transfer Agent
Computershare
P.O. Box 505000
Louisville, KY 40233-5000
T: (781) 575-2879
www-us.computershare.com

Stockholder Inquiries
Questions regarding stock transfer requirements, lost certificates and change of address should be directed to the transfer agent, Computershare. Other stockholder or investor inquiries, including requests for our filings with the U.S. Securities and Exchange Commission or other information, should be directed to ir@athersys.com.

Stock Listing
The Company's common stock trades on the NASDAQ Capital Market under the symbol "ATHX".

Athersys.com
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Cleveland, OH 44115-2634