ATHERSYS, INC / NEW
Form 10-K
March 15, 2019
Table of Contents

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

FORM 10-K

(Mark one)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
OR
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number 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 x
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 x
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 x No
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x 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	x
Non-accelerated filer	Smaller reporting company	x
	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 x

The aggregate market value at June 29, 2018, 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 $1.97 of such stock as quoted on the NASDAQ Capital Market on such date) held by non-affiliates of the registrant was approximately $245.4 million.

The registrant had 146,842,739 shares of common stock outstanding on March 7, 2019.

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 2019 annual meeting of stockholders.

Table of Contents

ATHERSYS, INC.

Unless otherwise stated or the context otherwise indicates, all references in this Annual Report on Form 10-K to "Athersys," "us," "our," "we" or "the Company" mean Athersys, Inc. and its subsidiaries.

TABLE OF CONTENTS

Table of Contents

PART I

ITEM 1. BUSINESS

We are an international biotechnology company that is focused 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 and have established a portfolio of therapeutic product development programs to address significant unmet medical needs in multiple disease areas. Our MultiStem® cell therapy, a patented and proprietary allogeneic stem cell product, is our lead platform product and is currently in clinical development. Our most advanced program is focused on the treatment of ischemic stroke, which is currently being evaluated in a registrational trial in Japan, and in a Phase 3 clinical trial in North America under a Special Protocol Assessment, or SPA, and Europe. 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 cell 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 and regulate other cell types. 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 several distinct mechanisms acting in parallel, resulting in a more effective therapeutic response.

We believe the therapeutic and commercial potential for MultiStem cell therapy to be very broad, applying to multiple 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 consistently 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 both clinical and preclinical 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 cell therapy to be used as a treatment of acute and chronic forms of neurological conditions or injury, cardiovascular disease, inflammatory and immune disorders, and certain pulmonary conditions. 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, which is our most advanced area, we have an ongoing Phase 3 clinical trial to evaluate the potential for MultiStem treatment of patients who have suffered neurological damage from an ischemic stroke. The results from our completed Phase 2 study demonstrated favorable tolerability and safety for MultiStem, consistent with the results from prior studies. While the Phase 2 study did not achieve the primary 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 reduced post-stroke inflammation compared to placebo, and the results suggest that this effect was more pronounced for subjects who received 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.

Table of Contents

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 MultiStem cell therapy is proven effective in our ongoing Phase 3 registrational study and if it receives a marketing authorization from the United States Food and Drug Administration, or FDA, this treatment window would make this therapy available to most ischemic stroke patients, in contrast to other therapies (e.g., tissue plasminogen activator, or tPA, or mechanical thrombectomy), which have shorter treatment windows.

Since 2016, we have had a collaboration with HEALIOS K.K., or Healios, to develop and commercialize MultiStem for the treatment of certain indications in Japan. Healios has a license to our technology and is responsible for the development and commercialization of MultiStem for ischemic stroke and acute respiratory distress syndrome, or ARDS, in Japan on an exclusive basis, and we are responsible for the supply of clinical product to Healios. An expansion of our Healios collaboration in June 2018 included, among other things, an exclusive license to our technology for the development and commercialization of additional indications, including (i) ARDS in Japan as noted above, (ii) certain ophthalmological indications worldwide, (iii) the treatment of diseases of the liver, kidney, pancreas and intestinal tissue through administration of our products in combination with cells derived from induced pluripotent stem cells, or iPSC, in Japan, and (iv) the use of MultiStem cells for Healios' organ bud technology for all organ diseases worldwide. In addition to up-front license fees received under our arrangement with Healios, we receive payments for product supply and other manufacturing services provided, as well as potential milestone achievement and royalties on net sales that vary among the licensed indications. Furthermore, Healios has a right of first negotiation that currently expires in June 2019 for an exclusive option to license certain disease indications for development and commercialization in China.

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 $21.1 million. The warrants were not exercisable at issuance, but instead become exercisable based upon certain objectives related to the expansion of the collaboration. Currently, 4,000,000 of the warrants are exercisable.

We have worked closely with Healios to support their development efforts in Japan. In 2016, the Pharmaceuticals and Medical Devices Agency, or PMDA, authorized the Clinical Trial Notification, 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 of the product candidate, is currently ongoing and enrolling patients in Japan. 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, Healios' ischemic stroke program has been awarded the SAKIGAKE designation by the PMDA, which is designed to expedite regulatory review and development and is analogous to Fast Track designation from the FDA.

While Healios is conducting its TREASURE study, our Phase 3 trial is ongoing in the United States, with plans to expand the study internationally. Following the completion of our Phase 2 trial, or MASTERS-1, we advanced our development efforts in North America and Europe by engaging in discussions with the FDA, the European Medicines Agency, or EMA, and other regulators. We received agreement from the FDA under a SPA for the design and planned analysis of our pivotal Phase 3 clinical study of MultiStem for ischemic stroke entitled, "MultiStem Administration for Stroke Treatment and Enhanced Recovery Study-2," or MASTERS-2, meaning that the trial is adequately designed to support a Biologic License Application, or BLA, submission for registration if it is successful. The FDA also 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 BLA, facilitating a timely regulatory

review. This program subsequently received the Regenerative Medicine Advanced Therapy, or 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 effectively address unmet medical needs for a serious or life threatening disease or condition. The RMAT designation is the equivalent of the non-regenerative medicine product's Breakthrough Therapy designation, 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. The design of MASTERS-2 has also received a Final Scientific Advice positive opinion from the EMA, representing the EMA’s

Table of Contents

agreement that successful results from the trial could result in registration and marketing approval of the MultiStem cell 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.

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 January 2019, we announced summary results from our exploratory clinical study of the intravenous administration of MultiStem cell therapy to treat patients who are suffering from ARDS. The study results provide further confirmation of tolerability and a favorable safety profile associated with MultiStem treatment. Importantly, MultiStem subjects had lower mortality and a greater number of ventilator-free and ICU-free days in the first month following diagnosis compared to patients receiving placebo. Furthermore, analysis of initial biomarker data reflects lower levels of inflammatory markers/cytokines following MultiStem treatment, an expected mechanism of action in this patient population. ARDS is a serious immunological and inflammatory condition characterized by widespread inflammation in the lungs. ARDS can be triggered by pneumonia, sepsis, trauma or other events, 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 the high treatment costs of ARDS, a successful cell therapy could be expected to generate significant savings for the healthcare system by reducing days on a ventilator and in the ICU and importantly, could reduce mortality and improve quality of life for those suffering from the condition. ARDS affects annually approximately 400,000 - 500,000 patients in Europe, the United States and Japan.

In 2018, we announced with the University of Texas Health Science Center at Houston, or UTHealth, our plans to conduct a Phase 2 clinical trial evaluating MultiStem cell therapy for early treatment and prevention of complications after severe traumatic injury. This first-ever study of a cell therapy for treatment of a variety of traumatic injuries is intended to be conducted at Memorial Hermann-Texas Medical Center, one of the busiest Level 1 trauma centers in the United States. The study has grant support from the Medical Technology Enterprise Consortium and the Memorial Hermann Foundation. We intend to provide the clinical product for the conduct of the trial, as well as regulatory and operational support. We are in the planning and preparation stage for this study, which we expect to be initiated in 2019, and will provide further updates as preparations for the trial progress.

In addition to these programs, 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. 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 evidence of therapeutic benefit among patients with severely compromised heart function.

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, or HSC, transplant to treat leukemia or certain other blood-borne cancers. Our MultiStem cell therapy for GvHD has been designated an orphan drug by both the FDA and the EMA for the prevention of GvHD, which may provide market exclusivity and other substantial potential incentives and benefits. Also, the MultiStem product was granted Fast Track designation by the FDA for prophylactic administration to prevent or minimize GvHD following HSC transplantation. Subsequently, our registration study design received a positive opinion from the EMA through the Protocol Assessment/Scientific Advice procedure. Furthermore, the proposed Phase 2/3 registration study received a SPA from the FDA. Initiation of this trial will depend on the progress in other clinical trials, the achievement of certain business development and financial objectives, and the development and success of alternative treatment options for GvHD that would reduce the need for transplant procedures. We may elect to enter into a development and commercialization collaboration to further advance this program.

MultiStem cell therapy 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. Our current policy precludes the administration of MultiStem to patients on a compassionate use basis, primarily for financial and logistical reasons, although we reserve the right to amend this policy in the future if circumstances warrant.

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.

Table of Contents

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 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 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. Japan's Regenerative Medicine regulatory framework enacted in 2014 has already resulted in the commercial approval of multiple cell therapy products developed by other companies that we are aware of, along with coverage and 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 cell therapy, and continue to evaluate partnering opportunities related to certain programs. For some programs we may elect to fund further development in specific 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 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 scaled, commercial manufacturing. We may partner with other companies to complete such development and preparation activities, 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 conduct our 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 are expected to have benefit, such as we have done with ARDS. 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 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. 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 Create Value. 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

Table of Contents

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 have entered into licensing arrangements with companies such as Healios, Chugai Pharmaceutical Co., Ltd., Pfizer Inc., or Pfizer, Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Johnson & Johnson, Wyeth Pharmaceuticals Inc., (now part of Pfizer), RTI Surgical, Inc., or RTI, and others. Licensing partnerships generate revenue and provide capital that helps enable 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 cell therapy has shown promise in many disease areas, including in 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. 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, UTHealth, the University of Pittsburgh Medical Center, the Katholieke Universiteit Leuven, University of Regensburg, and other institutions. Through this network of collaborations, we have evaluated MultiStem cell 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 technologies, applications and intellectual property and enable us to file patent applications that cover new applications of our existing technologies or product candidates, including MultiStem cell therapy and other opportunities. We currently have over 310 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, certain pulmonary conditions and other conditions where the current standard of care is limited or inadequate for many patients. Our programs in the clinical development stage include the following:

- Ischemic Stroke: We launched our pivotal Phase 3 clinical trial of MultiStem cell therapy for the treatment of ischemic stroke, referred to as MASTERS-2, and enrollment commenced in the third quarter of 2018. We are initiating the study with a small number of high-enrolling sites and plan to bring on additional sites over time in line with clinical product supply and clinical operations objectives. The MASTERS-2 study has received several regulatory distinctions including SPA, Fast Track designation and RMAT from the FDA, as well as a Final Scientific Advice positive opinion from the EMA, described further below. 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.

We received agreement from the FDA under a SPA for the design and planned analysis of our MASTERS-2 pivotal Phase 3 trial. The SPA provides agreement from the FDA that the protocol design, clinical endpoints, planned conduct and statistical analyses encompassed in MASTERS-2 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. The FDA has also 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 BLA facilitating a

Table of Contents

timely regulatory review. The design of MASTERS-2 has also received a Final Scientific Advice positive opinion from the EMA, representing the EMA's agreement that successful results from the trial could result in registration and marketing approval of the MultiStem cell 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. We subsequently received 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 effectively address unmet medical needs for a serious or life threatening disease or condition. The RMAT designation is the equivalent of the non-regenerative medicine product's Breakthrough Therapy designation, 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.

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

Healios' ongoing TREASURE study in Japan is being conducted at hospitals in Japan that have extensive experience in providing care for stroke victims. Enrolled subjects are receiving 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 in this 220 patient, randomized, double-blind, placebo-controlled trial. 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 trial could lead to registration under Japan's Regenerative Medicine regulatory framework, which 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, Healios' ischemic stroke program has been awarded the SAKIGAKE designation by the PMDA, which is designed to expedite regulatory review and approval, and is analogous to Fast Track designation from the FDA. We look forward to completing both the MASTERS-2 and TREASURE trials and using the accelerated pathway afforded to us by the regulators in the United States, Europe and Japan upon study completion.

- ARDS: In January 2019, we announced summary results from our exploratory clinical study of the intravenous administration of MultiStem cell therapy to treat patients who are suffering from ARDS. The study results provide further confirmation of tolerability and a favorable safety profile associated with MultiStem treatment. Importantly, MultiStem subjects had lower mortality and a greater number of ventilator-free and ICU-free days in the first month following diagnosis compared to patients receiving placebo. Furthermore, analysis of initial biomarker data reflects lower levels of inflammatory markers/cytokines following MultiStem treatment, an expected mechanism of action in this patient population. We will continue to evaluate the data as the one-year follow-up period is completed for all patients in the trial and plan to present additional results after further analyses. Healios has a license to develop and commercialize ARDS in Japan and announced in November 2018 its plans to initiate in the first half of 2019 a clinical trial of MultiStem for patients with pneumonia-induced ARDS.
- Trauma: In 2018, we announced with UTHealth our plans to conduct a Phase 2 clinical trial evaluating MultiStem cell therapy for early treatment and prevention of complications after severe traumatic injury. This first-ever study of a cell therapy for treatment of a wide range of traumatic injuries is intended to be conducted at Memorial

Hermann-Texas Medical Center, one of the busiest Level 1 trauma centers in the United States. The study has grant support from the Medical Technology Enterprise Consortium and the Memorial Hermann Foundation. We intend to provide the clinical product for the conduct of the trial, as well as regulatory and operational support. We and UTHealth are in the planning and preparation stage for this study and will provide further updates as preparations for the trial progress.

- AMI: We are conducting an ongoing Phase 2 clinical study in the United States for the administration of MultiStem cell therapy to patients that have suffered a heart attack. In a previously completed Phase 1 clinical study, the results

Table of Contents

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. The double-blind, sham-controlled Phase 2 clinical study is currently enrolling patients, however, enrollment rates have continued to be below expectations due in part to changes in standard of care. We are evaluating our options related to this trial and will provide updates regarding the conduct of the study, as appropriate.

- HSC Transplant / GvHD: Currently, this program is staged for future registration-directed development, which depends on the success and impact of potential alternative therapies for treating the underlying conditions leading to transplant, as well as other business and financial considerations. Following our completed 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 HSC transplant, 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 HSC transplantation. Subsequently, our registration study design received a positive Scientific Advice opinion from the EMA and a SPA designation from the FDA.

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.

We are engaged in preclinical development and evaluation of MultiStem cell therapy in other indications, 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 cell therapy for various programs and may enter into one or more business partnerships to advance these programs over time. We may also elect to advance the development of certain programs independently.

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 our and our partners' clinical trials or commercial activities.

Our collaboration with Healios initially covered MultiStem cell therapy for ischemic stroke in Japan and the use of our technology for Healios’ organ bud program targeted to liver disease. In June 2018, the collaboration was expanded to include a license to our technologies for ARDS treatment and for additional indications for its organ bud technology, as well as certain other rights, including a license for the use of our MultiStem product to treat certain ophthalmological indications and a license to treat diseases of the liver, kidney, pancreas and intestinal tissue through administration of our products in combination with iPSC-derived cells. We provide manufacturing services and supply Healios with clinical product for the licensed indications, and in the event that 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 its licensed fields and territories. Healios also has a right of first negotiation that currently expires in June 2019 for an option to license certain indications 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 have received royalty revenue from product sales and a payment associated with achievement of a commercial milestone. However, RTI has announced that it will

cease distribution of its bone graft product that utilizes our technology, presumably for regulatory reasons.

Table of Contents

Regenerative Medicine Programs

MultiStem — A Novel Therapeutic Modality

We are developing our MultiStem cell 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 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 cell therapy include the treatment of 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. We believe that MultiStem cell therapy represents a significant advancement in the field of stem cell therapy. We currently have open Investigational New Drug Applications, or INDs, for the study of MultiStem administration in distinct clinical indications, and multiple clinical trials are ongoing.

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 HSCs, 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 cell technologies have been able to achieve.
- “Off-the-shelf” utility. Unlike traditional bone marrow or HSC transplants that require extensive genetic matching between donor and recipient, MultiStem administration does not require tissue matching or administration of 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. Certain 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 many years of preclinical study in a range of animal models by a variety of investigators and that is supported by clinical data from multiple studies 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 prequalified, healthy, consenting donor, and these cells are then expanded to form a master cell bank from which we subsequently produce clinical grade material. We have 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

nonimmunogenic 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 years, we believe that MultiStem cell therapy has the potential to treat a range of distinct disease indications. As a result, we believe we will be

Table of Contents

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, Inflammatory and Immune Disorders, Certain Pulmonary Conditions and Other Conditions

Healthcare represents a significant part of the global economy. In the United States, it represented approximately 17.9% of all economic activity in 2017, or about $3.5 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 to study the impact of MultiStem cell therapy in a range of preclinical models that reflect various types of human disease or injury. 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.

Based on preclinical results, we have advanced MultiStem cell therapy to clinical development stage in several clinical indications or disease areas, including treatment of ischemic stroke caused by a blockage of blood flow in the brain; ARDS; complications from trauma; damage caused by myocardial infarction; certain complications associated with traditional bone marrow or HSC transplantation; inflammatory bowel disease, initially focused on patients suffering from severe, treatment refractory ulcerative colitis; and to treat or prevent certain complications associated with solid organ transplant. 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 substantial 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 from time-to-time in support of this work, including 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 cell 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. According to the 2018 American Heart Association, or AHA, statistical update, there are approximately 800,000 individuals in

Table of Contents

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 new treatments that improve the prognosis for stroke victims. The only FDA-approved drug currently available for treating 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 dissolve the clot. Administration of tPA beyond the early treatment window is not recommended, since it can cause cerebral bleeding or even death. Recent advancements in the development of mechanical clot retrievers and extraction devices may help additional patients, but such treatments are limited to certain types of strokes and to an early time window as well. As a consequence of these limited time windows, only a small percentage of stroke victims are treated successfully with the currently available therapies—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, 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. Preclinical research results 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 these results 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 ischemic stroke, MASTERS-1, which was a randomized, 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 have an ongoing pivotal Phase 3 clinical trial, referred to as MASTERS-2, which if successful and if the product is approved for commercialization, could 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

Table of Contents

barrier. With grant funding from the National Institutes of Health, or NIH, we further advanced our MultiStem programs and cell therapy platform, including further development of MultiStem cell 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. We have published findings 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, we also published an article that provides further evidence that our cell therapy has 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 cell 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.

Inflammatory and Immunological Disorders — MultiStem for Acute Respiratory Distress, Trauma Complications, HSC Transplant Support and other indications

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, Inflammatory Bowel Disease). Still other conditions may reflect complications associated with other diseases or trauma or 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 cell 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 the high treatment costs of ARDS, 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

Table of Contents

affects annually approximately 33,000 patients in the UK and 400,000 - 500,000 patients in Europe, the United States and Japan, alone.

In January 2019, we announced summary results from our exploratory clinical study of the intravenous administration of MultiStem cell therapy to treat patients who are suffering from ARDS. The study results provide further confirmation of tolerability and a favorable safety profile associated with MultiStem treatment. Importantly, MultiStem subjects had lower mortality and a greater number of ventilator-free and ICU-free days in the first month following diagnosis compared to patients receiving placebo. Furthermore, analysis of initial biomarker data reflects lower levels of inflammatory markers/cytokines following MultiStem treatment, an expected mechanism of action in this patient population.

Our research and others' research suggest that the activation of an acute hyperinflammatory response involving the peripheral immune system is a conserved biological response that occurs across multiple forms of trauma. For example, a common complication among trauma victims is Systemic Inflammatory Response Syndrome, which can contribute to or play a causative role in impaired organ system function, organ failure, or even multi-organ failure. We believe MultiStem can help address this systemic inflammatory response and its complications, and also promote better recovery following trauma. In 2018, we announced that the Department of Defense, through the Medical Technology Enterprise Consortium, plans to provide funding for a Phase 2 clinical trial to evaluate the administration of MultiStem cell therapy for early treatment and prevention of complications after severe traumatic injury, in collaboration with UTHealth. This first-ever study of a cell therapy for treatment of a wide range of traumatic injuries will be conducted at Memorial Hermann-Texas Medical Center, one of the busiest Level 1 trauma centers in the United States. We will provide the investigational clinical product for the conduct of the trial, as well as regulatory and operational support, as our contribution to the trial. The objective of the clinical study is to evaluate the safety and effectiveness of MultiStem for the treatment of severely injured patients for the prevention and early treatment of complications after severe traumatic injury. The proposed study is anticipated to be a randomized, double-blind, placebo-controlled Phase 2 clinical trial estimated to enroll approximately 150 severely-injured trauma patients within hours of hospitalization who have survived initial treatment and are admitted to the ICU. The proposed Phase 2 clinical trial must go through review and approval by the FDA, and therefore, the design is not yet final. We anticipate obtaining regulatory authorization to commence this trial in 2019 and subsequently initiate the trial.

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 HSC 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. 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

Table of Contents

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 the MultiStem product was granted Fast Track designation by the FDA for prophylaxis therapy against GvHD following HSC transplantation. Subsequently, our registration study design received a positive opinion from the EMA through the Protocol Assessment/Scientific Advice procedure. Furthermore, 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.

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, over one million people suffer a heart attack each year, according to the AHA 2018 Statistical Update. There were approximately 836,500 deaths (or approximately 1 of every 3 deaths in the United States) that occurred from all forms of cardiovascular disease, including approximately 366,800 individuals that died as a result of coronary heart disease. Heart disease remains the leading cause of death in the United States.

In a Phase 1 clinical trial we conducted previously, we explored MultiStem treatment for damage caused by AMI. Myocardial infarction, more commonly referred to as a heart attack, 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, where 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. We are currently conducting a Phase 2 clinical study for the administration of MultiStem cell therapy to patients that have suffered an AMI, which had been supported by a grant from the NIH that has now concluded, and we are 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 in the United States.

Other Programs

Animal Health Care

While development of our clinical programs for human health indications remains our priority, based on our research to date and work performed at our Belgian subsidiary, ReGenesys, we have demonstrated in preclinical animal health models that MultiStem cell therapy can promote tissue repair and healing that could provide meaningful benefits to animal patients, including those suffering from serious conditions with unmet medical need. According to Future Market Insights 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.

Collaborations and Partnerships

Healios

We have entered into a series of agreements with Healios, our collaborator in Japan and currently our largest stockholder. Under the collaboration that began in 2016, Healios is responsible for the development and commercialization of the

Table of Contents

MultiStem product for the licensed fields in the licensed territories, and we provide manufacturing services to Healios, currently comprising the supply of product for its clinical trials and the transfer of technology to a contract manufacturer in Japan to produce product for Healios, and we are compensated for these services.

In 2016, we entered into a license agreement, or First 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 Multipotent Adult Progenitor Cell, or MAPC, technology for use in Healios' "organ bud" program worldwide, initially for transplantation to treat liver disease or dysfunction. Under the First License Agreement, Healios also obtained a right to expand the scope of the collaboration, and Healios exercised this right in June 2018. Upon the expansion in June 2018, which was broader than that contemplated in the First License Agreement, we entered into the Collaboration Expansion Agreement, or CEA. Through the CEA, Healios (i) expanded its First License Agreement to include ARDS in Japan and expanded the "organ bud" license to include all transplantation indications; (ii) obtained a worldwide exclusive license, or the Ophthalmology License Agreement, for use of MultiStem product to treat certain ophthalmological indications; (iii) obtained an exclusive license in Japan, or the Combination Product License Agreement, for use of the MultiStem product to treat diseases of the liver, kidney, pancreas and intestinal tissue through local administration of MultiStem cell therapy in combination with iPSC-derived cells; (iv) obtained an exclusive, time-limited right of first negotiation, or ROFN Period, to enter into an option for a license to develop and commercialize certain MultiStem treatments in China; and (v) received certain other rights, including an additional non-therapeutic technology license. For all indications, Healios is responsible for the costs of clinical development in its licensed territories, and we provide manufacturing services to Healios.

Each license agreement with Healios has defined economic terms. Under the First License Agreement that related primarily to the license to ischemic stroke in Japan, we received a nonrefundable, up-front cash payment of $15 million, and upon the inclusion of the ARDS field in Japan, we received a nonrefundable, up-front cash payment of $10 million. For the additional rights granted to Healios under the CEA, including the Ophthalmology License Agreement and the Combination Product License Agreement, Healios paid us an additional nonrefundable, up-front payment of $10 million, which was paid in four quarterly installment payments of $2.5 million. Healios may elect to credit up to $10 million against milestone payments that may become due under the First License Agreement, as expanded to include ARDS, with limitations on amounts that may be credited to earlier milestone payments versus later milestone payments.

For each of the ischemic stroke indication and the ARDS indication, we may receive aggregate success-based regulatory filing and approval milestones up to $50 million and potential sales milestones up to $175 million, amounting to $225 million for each indication, subject to potential milestone credits. Milestone payments for all indications under the collaboration are non-refundable and non-creditable towards future royalties or any other payment due from Healios. For each of the ischemic stroke indication and the ARDS indication, we are entitled to receive tiered royalties on product sales, starting in the low double digits and increasing incrementally into the high teens depending on net sales levels and other factors.

The Ophthalmology License Agreement granted Healios worldwide, exclusive rights to treat certain ophthalmological diseases, by using either MultiStem cell therapy on a standalone basis or MultiStem in combination with retinal pigment epithelium cells derived from either iPSC or embryonic stem cells. For the standalone products, we will be entitled to receive success-based regulatory filing and approval milestones aggregating up to $48.1 million, potential sales milestones of up to $87.5 million, and tiered royalties on product sales in the single digits depending on net sales levels. For the combination opthalmology products, we are entitled to receive a low single-digit royalty, but no milestone payments.

The Combination Product License Agreement granted Healios exclusive rights in Japan to treat diseases of the liver, kidney, pancreas and intestinal tissue through local administration of MultiStem cell therapy in combination with iPSC-derived cells through certain delivery methods. We are entitled to receive a low single-digit royalty on net sales of the combination product treatments, but no milestone payments.

For the "organ bud" product, we are entitled to receive a fractional royalty on net sales of the "organ bud" products. For all indications, we may 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 First License 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, or EU. Under the CEA, the ROFN Period with respect to the option for a license in China was initially to expire on September 1, 2018, but was extended to June 30, 2019 in exchange for a $2.0 million payment from Healios that we received in December 2018. Furthermore, Healios may make an additional payment of $3.0 million to extend the ROFN Period for another six months through December 31, 2019. All such extension payments would be creditable against the option fee payable by Healios upon execution of the China option agreement, if applicable, or alternatively, Healios may apply the extension payment amounts as credits against any regulatory approval or commercial milestones for any licensed program, subject to certain limitations.

Table of Contents

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, or the Healios Warrant, for $21.1 million, or approximately $1.76 per share. The Healios Warrant, however, was not effective until the expansion agreements that were planned at that time under a letter of intent were effective. In June 2018, upon entry into the CEA, we amended the terms of the Healios Warrant such that (i) it would not be exercisable with respect to 16,000,000 shares unless during the ROFN Period, we and Healios have entered into an option agreement for a license to commercialize certain MultiStem treatments in China, and (ii) it would only be exercisable with respect to 4,000,000 shares at an exercise price equal to a reference price (which is generally 110% of the average closing price per share of our common stock for the ten trading days ending on the trading day immediately preceding the date the Healios Warrant is exercised), but no less than $1.76 per share. The Healios Warrant has an overall expiration date in September 2020, as defined, fixed and floating exercise price mechanisms, and an exercise cap triggered at Healios' ownership of 19.9% of our common stock. As of December 31, 2018, 1,500,000 of the 16,000,000 shares underlying the Healios Warrant will no longer be exercisable according to the terms of the agreement. The Healios Warrant may be terminated by us under certain conditions.

In 2017, we signed a clinical trial supply agreement for delivering the planned manufacturing services for Healios' clinical trial in Japan treating ischemic stroke patients, which was amended in 2018 to also include the clinical trial supply for Healios' clinical trial treating ARDS patients. The agreement includes the cost-sharing arrangement associated with our supply of clinical product for Healios' TREASURE study in Japan, including Healios' right to apply cost-share payments as a credit against certain milestone payments that may become due for the stroke indication under the First License Agreement, and if so applied, a stroke sales milestone would be increased, as defined. Alternatively, such cost-share payments may be repaid by us at our election. We are using commercially reasonable efforts to supply manufactured product to Healios. 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 areas. Services to Healios under the clinical trial supply agreement are ongoing.

Also in 2017, we entered into a technology transfer services agreement with Healios, in which Healios provides financial support to establish a contract manufacturer in Japan to produce product for Healios. At that time, we also amended the First License Agreement to confer to Healios a limited license to manufacture MultiStem in the event that we are acquired by a third-party. The parties have also agreed to discuss the appropriate time and content of a separate agreement regarding the transfer of certain manufacturing technology from Athersys to a contract manufacturer located in Japan. Services to Healios under the technology transfer services agreement are ongoing.

The First License Agreement will expire automatically when there are no remaining intellectual property rights subject to the license. Additionally, Healios may terminate the First License Agreement under certain circumstances, including for material breach and without cause upon advance written notice. We may terminate the First License Agreement if there is an uncured material breach of the agreement by Healios. Following the expiration or termination of the First License Agreement, Healios shall pay reduced royalties for continued use of our trademarks.

Following termination of the First License Agreement, the licenses granted to Healios to develop and commercialize MultiStem in Japan for ischemic stroke and for ARDS will terminate. Healios will transfer ownership to us 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.

The Ophthalmology License Agreement and Combination Product License Agreement will expire with respect to each licensed product in each country upon the latest of four events: (i) expiration of our applicable pre-existing patents, (ii) expiration of our applicable patents filed after the effective date, (iii) loss of all data or other regulatory exclusivity, and (iv) 10 years after first commercial sale. Each agreement may expire earlier for products in territories upon certain defined conditions related to the availability of alternative products. Each agreement would terminate in its entirety when all such product terms for each territory have expired. After expiration of a product in a territory, or the agreement as a whole, Healios' licenses remain in effect and Healios remains obligated to pay royalties at a reduced rate, and for a limited time, at which time the exclusive nature of the licenses convert to non-exclusive. Additionally,

Healios may terminate the agreements under certain circumstances, including for material breach and without cause upon advance written notice (in which case Healios' licenses do not survive). We may terminate either of these agreements if there is an uncured material breach of an agreement by Healios (in which case Healios' licenses would not survive).

Table of Contents

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. Since 2014, we have been receiving tiered royalties based on a royalty rate starting in the mid-single digits and increasing into the mid-teens from RTI on worldwide commercial sales of implants using our technologies, and in the fourth quarter of 2017, our royalty rate increased as a result of reaching a milestone for product sales. Royalties are 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.

We have been eligible to receive commercial milestones aggregating an additional $34.5 million of payments upon successful achievement, following a commercial milestone payment of $1.0 million that we received in 2017. However, RTI has announced that it will cease distribution of its bone graft product that utilizes our technology, and as a result, we do not expect any further milestone payments. We may receive some royalty revenue as RTI completes its discontinuance activities.

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 may use the cell lines in its internal drug development programs and, in exchange, we may 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, particularly due to the late stage of this collaboration. As of December 31, 2018, 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.

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.

Table of Contents

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 SanBio, 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 310 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

Table of Contents

280 issued patents (of which 30 are United States patents) and more than 155 global patent applications around our stem cell technology and MultiStem product platform. This includes 27 United States patents and more than 244 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 were 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., or Garnet, to settle longstanding intellectual property disagreements between the parties. Over the past several years, we were 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 had 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 paid Garnet $0.5 million and issued 1,000,000 shares of our common stock in connection with the execution of the agreement in 2017. In 2018, we paid an additional $1.0 million and issued an additional 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 further 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 clinical trials, preclinical research, product manufacturing and process development for manufacturing, salaries and related personnel costs, legal expenses resulting from intellectual property application and maintenance processes, and laboratory supply and reagent costs, were $38.7 million in 2018, $27.8 million in 2017 and $24.8 million in 2016.

Table of Contents

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, for example, 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.

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 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 the 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.

Table of Contents

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, 2018, we employed 75 full-time employees, including 18 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 website, 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 Securities and Exchange Commission, or 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 website free of charge. In addition, this website 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 website. The SEC also maintains a website, 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 website referred to in this annual report on Form 10-K is not incorporated by reference into this annual report unless expressly noted.

Table of Contents

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 $24.3 million in 2018, $32.2 million in 2017 and $15.3 million in 2016. As of December 31, 2018, we had an accumulated deficit of $373.0 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 $13.4 million in 2018, $24.0 million in 2017 and $10.9 million in 2016.

At December 31, 2018, we had $51.1 million of cash and cash equivalents. However, we will need substantially more funding to advance our product candidates through development and into commercialization, including to put in place manufacturing capacity to support such commercial activity. 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 support 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;

23

Table of Contents

- expenses related to the establishment of sales and marketing capabilities for products awaiting approval or products that have been approved;
- expenses related to establishing manufacturing capabilities;
- 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 Fund LLC, or Aspire Capital, as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the purchase agreement on any given day and during the term of the agreement is limited. Additionally, we and Aspire Capital may not affect any sales of shares of our common stock under the purchase agreement during the continuance of an event of default. Even if we are able to access the over $89.5 million available under the arrangement as of February 28, 2019, 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.

Table of Contents

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 collaboration and licensing arrangement is with Healios to develop and commercialize MultiStem cell therapy for the treatment of ischemic stroke and ARDS in Japan, among other things, and we also have license agreements with third parties pursuant to which we in-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

Table of Contents

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

Table of Contents

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, 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 that 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. Similarly, we our our collaborators may inadvertently violate the guidelines of the foreign equivalent of the FDA's DDMAC, e.g., in Europe or Japan.

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 third parties 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.

Table of Contents

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

Table of Contents

we are unsuccessful in obtaining and maintaining these patents related to products and technologies, we may ultimately be unable to commercialize products that we are developing or may elect to develop in the future.

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

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

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

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

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

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

In addition to patents, we will substantially rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. However, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. To protect our trade secrets, we may enter into confidentiality agreements with employees, consultants and potential collaborators. However, these agreements may not provide meaningful protection of our

trade secrets or adequate remedies in the event of unauthorized use or disclosure of such information. Likewise, our trade secrets or know-how may become known through other

Table of Contents

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 Holding AG, Johnson & Johnson, Sanofi S.A. and GlaxoSmithKline plc, as well as smaller biotechnology or biopharmaceutical companies such as Celgene, Mesoblast, SanBio, 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.

Table of Contents

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. 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 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;

Table of Contents

- 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 were 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.

Table of Contents

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.

33

Table of Contents

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;

Table of Contents

- 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 United States and abroad, including the EU's General Data Protection Regulation. 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, 2018, we had U.S. federal net operating loss and research and development tax credit carryforwards of approximately $151.4 million and $10.0 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 2032 and 2038. Additionally, as of December 31, 2018, we had federal net operating loss carryforwards generated after 2017 of $16.8 million that have an indefinite life, but with usage limited to 80% of taxable income in any given year. We also had foreign net operating loss carryforwards of approximately $21.6 million. Such foreign net operating loss carryforwards do not expire. We also had state and city net operating loss carryforwards aggregating approximately $65.5 million. Such state and city net operating loss carryforwards may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2019 and 2038.

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 $116.8 million, research and development tax credits of $10.0 million, and state and local net operating loss carryforwards of $65.3 million since 2012 through December 31, 2018.

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 Healios, 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.

35

Table of Contents

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.

Table of Contents

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 2021. 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. With the extension signed in March 2019, the lease currently expires in July 2020, and we have an option to renew annually through July 2022. The annual rent in Belgium is approximately $196,000 and is subject to adjustments based on an inflationary index. Our total rent expense for all properties was $493,000 in 2018.

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.

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: 58

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 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.

John J. Harrington, Ph.D.

Age: 51

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

Table of Contents

William (BJ) Lehmann, Jr., J.D.
Age: 53
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., or McKinsey, 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: 55
Ms. Campbell joined Athersys in January 1998 and has served as our Senior Vice President of Finance since March 2016. Ms. Campbell joined us as 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 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 assisted 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.

Table of Contents

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."

Holders

As of February 28, 2019, there were approximately 507 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.

Unregistered Sales

Since 2011, we have had in place equity purchase agreements with Aspire Capital, which provide us the ability to sell shares of our common stock to Aspire Capital from time-to-time. During the quarter ended December 31, 2018, we sold an aggregate of 3,908,582 shares of common stock to Aspire Capital under our equity purchase agreement, generating aggregate proceeds of $7.1 million. Each issuance of these unregistered shares qualifies as an exempt transaction pursuant to Section 4(a)(2) of the Securities Act of 1933. Each issuance qualified for exemption under Section 4(a)(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.

ITEM 6. SELECTED FINANCIAL DATA

(in thousands, except per share data)

	Year Ended December 31,				
	2018	2017	2016	2015	2014
Consolidated Statement of Operations Data:					
Revenues:					
Contract revenue [1]	$23,737	$2,843	$16,238	$10,298	$286
Grant revenue	554	865	1,109	1,650	1,337
Total revenues	24,291	3,708	17,347	11,948	1,623
Costs and expenses:					
Research and development	38,656	27,841	24,838	21,316	23,366
General and administrative	10,442	8,466	7,835	7,536	6,909
Depreciation	855	684	382	267	360
Total costs and expenses	49,953	36,991	33,055	29,119	30,635
Gain from insurance proceeds, net	617	—	682	—	—
Loss from operations	(25,045)	(33,283)	(15,026)	(17,171)	(29,012)
Other income (expense):					
Income (expense) from change in fair value of warrants	—	728	(557)	772	6,591
Other income (expense), net	762	314	209	(61)	86
Loss before income taxes	(24,283)	(32,241)	(15,374)	(16,460)	(22,335)
Income tax benefit			37	38	253
Net loss	$(24,283)	$(32,241)	$(15,337)	$(16,422)	$(22,082)
Net loss per share, basic	$(0.18)	$(0.29)	$(0.18)	$(0.20)	$(0.29)
Weighted average shares outstanding, basic	136,641	112,053	84,715	82,144	76,955
Net loss per share, diluted	$(0.18)	$(0.29)	$(0.18)	$(0.20)	$(0.31)
Weighted average shares outstanding, diluted	136,641	112,053	84,715	82,851	78,541

Table of Contents

	December 31,				
	2018	2017	2016	2015	2014
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$51,059	$29,316	$14,753	$23,027	$26,127
Working capital, excluding note payable (2016 and prior)	42,365	21,107	9,405	19,251	22,556
Total assets	61,730	33,593	19,060	25,129	28,718
Warrant liabilities and note payable	—	—	1,004	839	3,131
Total stockholders' equity	43,116	23,376	11,181	19,724	20,895

(1) We adopted Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers, effective January 1, 2018 as further described in Note B to the consolidated financial statements. As a result, the recognized revenue in 2018 is not accounted for on the same basis as the prior years and is not comparable largely due to the timing of revenue recognition.

Table of Contents

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

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

Overview

We are an international biotechnology company that is focused primarily in the field of regenerative medicine. Our MultiStem® cell therapy, a patented and proprietary allogeneic stem cell product, is our lead platform product and is currently in clinical development in several areas, the most advance of which is an ongoing Phase 3 clinical trial for the treatment of ischemic stroke. Our current clinical development programs are focused on treating neurological conditions, cardiovascular disease, inflammatory and immune disorders, and certain pulmonary conditions where the current standard of care is limited or inadequate for many patients, particularly in the critical care segment.

Current Programs

Our MultiStem cell therapy product development programs in the clinical development stage include the following:

•Ischemic Stroke: We launched our pivotal Phase 3 clinical trial of MultiStem cell therapy for the treatment of ischemic stroke, referred to as MASTERS-2, and enrollment commenced in the third quarter of 2018. We initiated the study with a small number of high-enrolling sites and plan to bring on additional sites over time in line with clinical product supply and clinical operations objectives. Our MASTERS-2 clinical trial is a randomized, double-blind, placebo-controlled clinical trial designed to enroll 300 patients primarily in North America and Europe who have suffered moderate to moderate-severe ischemic stroke. The enrolled subjects are receiving 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 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.

The MASTERS-2 study has received several regulatory distinctions including SPA designation, Fast Track designation and RMAT designation, which was established under the 21st Century Cures Legislation from the FDA, as well as a Final Scientific Advice positive opinion from the EMA.

In addition, Healios has an ongoing clinical trial, TREASURE, evaluating the safety and efficacy of administration of MultiStem cell therapy for the treatment of ischemic stroke in Japan, and enrollment continues. TREASURE will be evaluated under the progressive framework for regenerative medicine therapies in Japan. Under the new framework, Healios' ischemic stroke program has been awarded the SAKIGAKE designation by the PMDA, which is designed to expedite regulatory review and approval, and is analogous to Fast Track designation from the FDA.

We look forward to completing both the MASTERS-2 and TREASURE trials and using the accelerated pathway afforded to us by the regulators in the United States, Europe and Japan upon study completion.

•ARDS: In January 2019, we announced summary results from our exploratory clinical study of the intravenous administration of MultiStem cell therapy to treat patients who are suffering from ARDS. The study results provide further confirmation of tolerability and a favorable safety profile associated with MultiStem treatment. Importantly, MultiStem subjects had lower mortality and a greater number of ventilator-free and ICU-free days in the first month following diagnosis compared to patients receiving placebo. Furthermore, analysis of initial biomarker data reflects lower levels of inflammatory markers/cytokines following MultiStem treatment, an expected mechanism of action in this patient population. We will continue to evaluate the data as the one-year follow-up period is completed for all patients in the trial and plan to present additional results after further analyses. Healios has a license to develop and commercialize ARDS in Japan and announced in November 2018 its plans to initiate in the first half of 2019 a clinical trial of MultiStem for patients with pneumonia-induced ARDS.

Table of Contents

•Trauma: In 2018, we announced with UTHealth our plans to conduct a Phase 2 clinical trial evaluating MultiStem cell therapy for early treatment and prevention of complications after severe traumatic injury. This first-ever study of a cell therapy for treatment of a wide range of traumatic injuries is intended to be conducted at Memorial Hermann-Texas Medical Center, one of the busiest Level 1 trauma centers in the United States. The study has grant support from the Medical Technology Enterprise Consortium and the Memorial Hermann Foundation. We intend to provide the clinical product for the conduct of the trial, as well as regulatory and operational support. We and UTHealth are in the planning and preparation stage for this study and will provide further updates as preparations for the trial progress.
•AMI: We are conducting an ongoing Phase 2 clinical study in the United States for the administration of MultiStem cell therapy to patients that have suffered a heart attack. In a previously completed Phase 1 clinical study, the results 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. The double-blind, sham-controlled Phase 2 clinical study is currently enrolling patients, however, enrollment rates have continued to be below expectations due in part to changes in standard of care. We are evaluating our options related to this trial and will provide updates regarding the conduct of the study, as appropriate.
•HSC Transplant / GvHD: Currently, this program is staged for future registration-directed development, which depends on the success and impact of potential alternative therapies for treating the underlying conditions leading to transplant, as well as other business and financial considerations. Following our completed 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 HSC transplant, 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 HSC transplantation. Subsequently, our registration study design received a positive Scientific Advice opinion from the EMA and a SPA designation from the FDA.

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.

We are engaged in preclinical development and evaluation of MultiStem cell therapy in other indications, 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 cell therapy for various programs and may enter into one or more business partnerships to advance these programs over time. We may also elect to advance the development of certain programs independently.

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 our and our partners' clinical trials or commercial activities.

We have a collaboration with Healios that initially covered MultiStem cell therapy for ischemic stroke in Japan and the use of our technology for Healios’ organ bud program targeted to liver disease. In June 2018, the collaboration was expanded to include a license to our technologies for ARDS treatment and for additional indications for its organ bud technology, as well as certain other rights, including a license for the use of our MultiStem product to treat certain

ophthalmological indications and a license to treat diseases of the liver, kidney, pancreas and intestinal tissue through administration of our products in combination with iPSC-derived cells. We provide manufacturing services and supply Healios with clinical product for the licensed indications, and in the event that 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 its licensed

Table of Contents

fields and territories. Healios also has a right of first negotiation that currently expires in June 2019 for an option to license certain indications 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 have received royalty revenue from product sales and and a payment associated with achievement of a commercial milestones. However, RTI has announced that it will cease distribution of its bone graft product that utilizes our technology. No milestones were achieved for the year ended December 31, 2018, and we expect the RTI royalties to cease.

Financial

We have entered into a series of agreements with Healios, our collaborator in Japan and currently our largest stockholder. Under the collaboration that began in 2016, Healios is responsible for the development and commercialization of the MultiStem product for the licensed fields in the licensed territories, and we provide manufacturing services to Healios for which we are compensated, a portion of which may be credited by Healios against potential future milestone payments, as defined. In 2016, we received license fees of $15 million, and in connection with the expansion of the collaboration in June 2018, we received license fees of $20 million, of which $10 million may be credited by Healios against potential future milestone payments.

Each license agreement with Healios has defined economic terms, and we may receive success-based milestone payments. While there is no assurance that we will receive milestone proceeds under the Healios collaboration, any milestone payment we receive is non-refundable and non-creditable towards future royalties or any other payment due from Healios. Also, we are entitled to receive tiered royalties on net product sales, as defined in the license agreements.

The ROFN Period, as extended, with respect to the option for a license in China expires in June 2019, and we received a $2.0 million payment from Healios in December 2018 for the most recent extension. Furthermore, Healios may make an additional payment of $3.0 million to extend the ROFN Period for another six months through December 31, 2019. All such extension payments would be creditable against the option fee payable by Healios upon execution of the China option agreement, if applicable, or otherwise, against milestone payments under the licensed programs.

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 $21.1 million, or approximately $1.76 per share. The Healios Warrant is (i) not exercisable with respect to 16,000,000 shares unless during the ROFN Period, we and Healios have entered into a China option agreement, and (ii) exercisable with respect to 4,000,000 shares at an exercise price equal to a reference price, as defined, but no less than $1.76 per share. As of December 31, 2018, 1,500,000 of the 16,000,000 shares underlying the Healios Warrant will no longer be exercisable according to the terms of the Healios Warrant.

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 equity purchase agreements in place since 2011 with Aspire Capital, which provide us the ability to sell shares to Aspire Capital from time-to-time, as appropriate. The current agreement was entered into in February 2018 and includes Aspire Capital's commitment to purchase up to an aggregate of $100 million of shares of 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, Aspire Capital invested $1.0 million to purchase 500,000 shares of common stock at $2.00 per share. During the years ended December 31, 2018, 2017 and 2016, we sold 8,708,582, 9,400,000, and 2,191,418 shares, respectively, to Aspire Capital at average prices of $1.78, $1.75 and $1.84 per share, respectively. As of February 28, 2019, we had 18,050,000 million shares remaining to sell to Aspire Capital under the 2018 agreement.

During the year ended December 31, 2017, we received proceeds of approximately $1.9 million from the exercise of warrants. All of our previously outstanding warrants were either exercised prior to expiration or expired in March 2017, and we had only the Healios Warrant outstanding at December 31, 2018.

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 2018, we received an additional $0.6 million in insurance proceeds, net of associated expenses.

Table of Contents

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 have received royalties on commercial sales by a licensee of products using our technologies, which we expect to cease in connection with the licensees strategic transformation. 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, manufacture our product candidates and prepare for potential commercialization of our MultiStem cell therapy product. 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, 2018 Compared to Year Ended December 31, 2017

Revenues. Revenues increased to $24.3 million for the year ended December 31, 2018 from $3.7 million in 2017. Our contract revenues from our collaboration with Healios increased $21.4 million year-over-year, reflecting the expansion of our collaboration in June 2018 to include several additional licensed indications, among other things. Absent any new collaborations, we expect our future contract revenue to be comprised primarily of revenues associated with our Healios collaboration. Our royalty and other contract revenue decreased in 2018 since 2017 included $1.0 million in milestone payments from RTI. Additionally, RTI has announced that it will cease distribution of its bone graft product that utilizes our technology, and therefore, royalty proceeds from RTI will cease. Grant revenue decreased by $0.3 million in the year ended December 31, 2018 compared to the year ended December 31, 2017, primarily due to completed 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 $38.7 million for the year ended December 31, 2018 from $27.8 million for the year ended December 31, 2017. The increase in research and development expenses year-over-year of 10.9 million related primarily to increased clinical trial and manufacturing process development costs of $11.4 million, increased personnel costs of $1.6 million and increased internal supply costs of $0.9 million. These increases were partially offset by a decrease in license fees of $3.7 million related to the settlement and license agreement with Garnet in 2017 with one-time payments of cash and stock that were concluded in 2018. Based on our current clinical development, manufacturing, process development and regulatory affairs plans, we expect our 2019 annual research and development expenses to be higher in 2019 compared to 2018, and such costs will vary over time based on clinical manufacturing campaigns, the timing and stage of clinical trials underway, manufacturing process development projects and regulatory initiatives. These variations in activity level may also impact our accounts payable, accrued expenses and prepaid expenses balances from period-to-period. 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 $10.4 million in 2018 from $8.5 million in 2017. The $1.9 million increase was due primarily to increases in personnel costs, legal and professional services and stock compensation expense. We expect our general and administrative expenses may increase in 2019 related to personnel costs.

Depreciation. Depreciation expense increased to $0.9 million in 2018 from $0.7 million in 2017 primarily due to equipment purchases.

Income (Expense) from Change in Fair Value of Warrants, net. We did not recognize a change in fair value of warrants during the year ended December 31, 2018, since our only outstanding warrant, the Healios Warrant, is classified as equity. For the comparable period of 2017, we had $0.7 million of income for the market value change in our warrant liabilities for warrants that had either been exercised by or expired in 2017.

Gain from Insurance Proceeds, net. 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. In 2018, we received an additional $0.6 million in insurance proceeds, net of associated expenses, which concluded the insurance claim.

Table of Contents

Other Income, net. Other income, net, for the years ended December 31, 2018 and 2017 was $0.8 million and $0.3 million, respectively, and was comprised of interest income and expense, refundable foreign tax credits and foreign currency gains and losses.

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 other proceeds from our collaboration with Healios. 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.

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.

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.

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, net. 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 was 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, net. Other income, 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.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances. At December 31, 2018, we had $51.1 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 $373.0 million at December 31, 2018. 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 use all of our sources of capital to develop our technologies, discover and develop therapeutic product candidates, develop business collaborations and acquire certain technologies and assets.

As addressed herein, we received $10.0 million of license fees in June 2018 and another $10.0 million was received quarterly, thereafter, in connection with the expansion of our collaboration with Healios. We are also entitled to receive potential milestones payments, subject to certain credits, and royalties from Healios under our licensed programs. Furthermore, if Healios elects to enter into an option to license certain disease indications for development in China, for which Healios has a right of first negotiation that expires on June 30, 2019, we would receive additional proceeds. Healios paid us $2.0 million in December 2018 to extend its right of first negotiation for the China option to June 30, 2019 and has the ability to extend it further through December 31, 2019 for an additional $3.0 million payment. We also receive payments from Healios for clinical product supply and other manufacturing services.

Certain proceeds from Healios may be used by Healios to offset milestone payments that may become due in the future.

Table of Contents

In connection with the expansion, Healios purchased 12,000,000 shares of our common stock for $21.1 million and received the Healios Warrant to purchase up to 20,000,000 shares of common stock in March 2018, subject to certain conditions. The Healios Warrant is currently exercisable with respect to 4,000,000 shares underlying the Healios Warrant. As of December 31, 2018, of the 16,000,000 shares, 1,500,000 will no longer be exercisable according to the terms of the agreement and the remaining 14,500,000 shares will become exercisable only in the event that Healios executes an option to expand into the China territory. The Healios Warrant has an overall term that expires in September 2020, as defined, 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 Healios Warrant over its term, although there can be no assurances that Healios will exercise the Healios Warrant in whole or in part. As of December 31, 2018, no shares have been issued under the Healios Warrant.

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 includes Aspire Capital’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. During the years ended December 31, 2018 and 2017, we sold 8,708,582 and 9,400,000 shares, respectively, to Aspire Capital at average prices of $1.78 and $1.75 per share, respectively.

During the year ended December 31, 2017, we received proceeds of approximately $1.9 million from the exercise of warrants. All of our previously outstanding warrants were either exercised prior to expiration or expired in March 2017, and we had only the Healios Warrant outstanding at December 31, 2018.

We also have a collaboration with RTI for the development of products for certain orthopedic applications using our stem cell technologies in the bone graft substitutes market, and we have received royalty revenue from product sales and a payment associated with achievement of a commercial milestone. However, RTI has announced that it will cease distribution of its bone graft product that utilizes our technology.

We will require substantial additional funding in order to continue our research and product development programs, including clinical trials of our product candidates and process development and manufacturing projects, and to prepare for possible approval and commercial activities. At December 31, 2018, we had available cash and cash equivalents of $51.1 million, and we intend to meet our short-term liquidity needs with available cash. Over the longer term, we will continue to make use of available cash, but will have to continue to generate additional funding to meet our needs, through business development, collaborator achievement of milestones under our agreements, 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, equity offerings and Healios' potential exercise of its Healios Warrant from time to time. In January and February 2019, we generated an additional $3.3 million in proceeds from the use of our equity purchase arrangement. 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 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. Furthermore, delays in product supply for our and Healios' clinical trials may impact the timing and cost of such studies. 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.

Table of Contents

Cash Flow Analysis

Net cash used in operating activities was $13.4 million, $24.0 million and $10.9 million in 2018, 2017 and 2016, respectively, and represented the use of cash to fund operations, clinical trials, preclinical research and process development activities; net of receipts from collaborative arrangements, such as Healios. Net cash used in operating activities may fluctuate significantly period-to-period, 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. These variations in activity level may also impact our accounts payable, accrued expenses and prepaid expenses balances from period-to-period.

Net cash used in investing activities was $0.9 million, $0.3 million and $1.1 million in 2018, 2017 and 2016, respectively, related to the purchase of equipment for our manufacturing and process development activities, which was partially offset by insurance proceeds received in 2018 and 2016 related to the 2016 flood. We expect that our capital equipment expenditures will continue at a similar level in 2019 compared to 2018.

Financing activities provided net cash of $36.0 million in 2018, $38.9 million in 2017, and $3.7 million in 2016. In 2018, Healios invested $21.1 million in our common stock, and in 2017, we received $20.9 million of net proceeds from a common stock offering. Additional proceeds relate to the exercise of common stock warrants in 2017 and 2016 and equity sales to Aspire Capital in each of the three years, net of shares of common stock retained for withholding taxes on share-based awards.

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, product supply revenue, service revenue, cost-sharing, milestones and royalties. The deliverables under such an arrangement are evaluated under ASU 606, Revenue from Contracts with Customers. Each deliverable is evaluated 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 we expect to be entitled in exchange for those goods or services.

We have license and other agreements with Healios 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.

Contract Revenue from Healios: At the inception of the Healios arrangement and again each time that the arrangement has been modified, all material performance obligations are identified, which include (i) licenses to our technology, (ii) product supply services, and (iii) services to transfer technology to a contract manufacturer on Healios’ behalf. We determine whether the performance obligations are both capable of being distinct and distinct within the context of the contract. We develop assumptions that require judgment to determine the standalone selling price in order to account for our collaborative agreements, as these assumptions typically include probabilities of obtaining marketing approval for the product candidates, estimated timing of commercialization, estimated future cash flows from potential product sales of our product candidates, estimating the cost and markup of providing product supply and technical services, and appropriate discount rates.

In order to determine the transaction price, in addition to the fixed payments, we estimate the amount of variable consideration utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract, and the estimates for variable consideration are reassessed each reporting period. We constrain, or reduce, the estimates of

Table of Contents

variable consideration if it is probable that a significant reversal of previously recognized revenue could occur throughout the life of the contract, and both the likelihood and magnitude of a potential reversal of revenue are taken into consideration.

At inception and upon each modification date, once the estimated transaction price is established, amounts are allocated to each separate performance obligation on a relative standalone selling price basis. These performance obligations include any remaining, undelivered elements at the time of modifications and any new elements from a modification to the arrangement if the conditions are not met for being treated as a separate agreement.

For performance obligations satisfied over time, we apply an appropriate method of measuring progress each reporting period and, if necessary, adjust the estimates of performance and the related revenue recognition. Our technology transfer services are satisfied over time, and we recognize revenue in proportion to the contractual services provided. For performance obligations satisfied at a point in time (i.e., product supply), we recognize revenue upon delivery.

Royalty Revenue: 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.

Grant Revenue: Revenues from grants consist 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.

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.

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 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.

48

Table of Contents

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 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, which could negatively impact our trials and the trials of our collaborators;
- uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the treatment of ischemic stroke, ARDS, AMI and trauma, 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 work with Healios to reach an agreement for an option to license certain indications in China;
- 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 and generate sales related to our technologies;
- the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in North America, 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-K, 10-Q and 8-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.

Table of Contents

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, 2018, we had no investments. We have entered into loan arrangements with financial institutions when needed and when available to us. At December 31, 2018, we had no borrowings outstanding.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Athersys, Inc.
Consolidated Financial Statements
Years Ended December 31, 2018, 2017 and 2016
Contents

Table of 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. (the Company) as of December 31, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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 14, 2019 expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09

As discussed in Note B to the consolidated financial statements, the Company changed its method for recognizing revenue due to the adoption of ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), effective January 1, 2018.

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 14, 2019

Table of Contents

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.'s internal control over financial reporting as of December 31, 2018, 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. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.
We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and December 31, 2017, 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, 2018, and the related notes and financial statement schedule listed in the Index at Item 15(a)(2) and our report dated March 14, 2019 expressed an unqualified opinion thereon.
Basis for Opinion
The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying "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 14, 2019

Table of Contents

Athersys, Inc.
Consolidated Balance Sheets
(In Thousands, Except Share and Per Share Amounts)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$51,059	$29,316
Accounts receivable	262	586
Accounts receivable from Healios	1,108	153
Unbilled accounts receivable from Healios	3,620	—
Prepaid expenses and other	1,791	1,135
Total current assets	57,840	31,190
Equipment, net	3,002	2,206
Deposits and other	888	197
Total assets	$61,730	$33,593
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$9,163	$4,469
Accrued compensation and related benefits	1,901	1,065
Accrued clinical trial related costs	1,276	1,453
Accrued expenses	461	425
Accrued license fee expense	—	1,900
Deposit from Healios	2,000	—
Deferred revenue - Healios	674	521
Deferred revenue	—	250
Total current liabilities	15,475	10,083
Advance from Healios	3,139	134
Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at December 31, 2018 and 2017	—	—
Common stock, $0.001 par value; 300,000,000 shares authorized; 144,292,739 and 122,077,453 shares issued and outstanding at December 31, 2018 and 2017, respectively	144	122
Additional paid-in capital	416,014	373,884
Accumulated deficit	(373,042)	(350,630)
Total stockholders' equity	43,116	23,376
Total liabilities and stockholders' equity	$61,730	$33,593

See accompanying notes.

Table of Contents

Athersys, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In Thousands, Except Per Share Amounts)

	Years Ended December 31,		
	2018	2017	2016
Revenues			
Contract revenue from Healios	$22,276	$918	$16,238
Royalty and other contract revenue	1,461	1,925	—
Grant revenue	554	865	1,109
Total revenues	24,291	3,708	17,347
Costs and expenses			
Research and development (including stock compensation expense of $1,609, $1,232 and $1,192 in 2018, 2017 and 2016, respectively)	38,656	27,841	24,838
General and administrative (including stock compensation expense of $2,240, $1,812 and $1,676 in 2018, 2017 and 2016, respectively)	10,442	8,466	7,835
Depreciation	855	684	382
Total costs and expenses	49,953	36,991	33,055
Gain from insurance proceeds, net	617	—	682
Loss from operations	(25,045)	(33,283)	(15,026)
Income (expense) from change in fair value of warrants, net	—	728	(557)
Other income, net	762	314	209
Loss before income taxes	(24,283)	(32,241)	(15,374)
Income tax benefit	—	—	37
Net loss and comprehensive loss	$(24,283)	$(32,241)	$(15,337)
Net loss per common share, basic and diluted	$(0.18)	$(0.29)	$(0.18)
Weighted average shares outstanding, basic and diluted	136,641	112,053	84,715

See accompanying notes.

Table of Contents

Athersys, Inc.
Consolidated Statements of Stockholders' Equity
(In Thousands, Except Share Amounts)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Stated Value	Number of Shares	Par Value			
Balance at January 1, 2016	—	$ —	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 and warrants, 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
Cumulative effect of accounting change						1,871	1,871
Stock-based compensation	—	—	—	—	3,849	—	3,849
Issuance of warrant to Healios at fair value	—	—	—	—	1,080	—	1,080
Issuance of common stock, net of issuance costs	—	—	9,658,582	9	16,619	—	16,628
Issuance of common stock to Healios, net of issuance costs	—	—	12,000,000	12	20,983	—	20,995
Issuance of common stock under equity compensation plan	—	—	556,704	1	(401)	—	(400)
Net and comprehensive loss	—	—	—	—	—	(24,283)	(24,283)
Balance at December 31, 2018	—	$ —	144,292,739	$ 144	$ 416,014	$ (373,042)	$ 43,116

See accompanying notes.

Table of Contents

Athersys, Inc.
Consolidated Statements of Cash Flows
(In Thousands)

	Years Ended December 31,		
	2018	2017	2016
Operating activities			
Net loss	$(24,283)	$(32,241)	$(15,337)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	855	684	382
Gain from forgiveness of note payable	—	—	(190)
Stock-based compensation	3,849	3,044	2,868
Discount on revenue from issuance of warrant	1,080	—	—
Other	—	(22)	2
Stock–based patent license and settlement expense	315	3,150	—
Gain from insurance proceeds, net	(617)	—	(682)
Change in fair value of warrant liabilities	—	(728)	557
Changes in operating assets and liabilities:			
Accounts receivable	324	12	(237)
Accounts receivable from Healios - billed and unbilled	(4,545)	(153)	—
Prepaid expenses and other	(1,346)	(206)	(462)
Accounts payable and accrued expenses	4,269	1,537	2,413
Advances and deposits from Healios	4,889	134	—
Deferred revenue - Healios	2,110	—	—
Deferred revenue	(250)	771	(245)
Net cash used in operating activities	(13,350)	(24,018)	(10,931)
Investing activities			
Purchase of available-for-sale securities	—	—	(16,343)
Sales of available-for-sale securities	—	—	16,305
Proceeds from insurance, net	617	—	682
Purchases of equipment	(1,532)	(285)	(1,711)
Net cash used in investing activities	(915)	(285)	(1,067)
Financing activities			
Proceeds from issuance of common stock, net	15,415	37,287	4,028
Proceeds from issuance of common stock to Healios, net	20,995	—	—
Proceeds from exercise of warrants	—	1,862	163
Shares retained for withholding tax payments on stock-based awards	(402)	(283)	(467)
Net cash provided by financing activities	36,008	38,866	3,724
Increase (decrease) in cash and cash equivalents	21,743	14,563	(8,274)
Cash and cash equivalents at beginning of year	29,316	14,753	23,027
Cash and cash equivalents at end of year	$51,059	$29,316	$14,753

See accompanying notes.

Table of Contents

Athersys, Inc.
Notes to Consolidated Financial Statements
A. Background
We are an international biotechnology company focused in the field of regenerative medicine and operate in one business segment. Our operations consist of research, preclinical development and clinical development activities, and our most advanced program is in Phase 3 clinical development.
We have incurred losses since our inception in 1995 and had an accumulated deficit of $373.0 million at December 31, 2018. We will require additional capital to continue our research and development programs, including progressing our clinical product candidates to commercialization and preparing for commercial-scale manufacturing and sales. At December 31, 2018, we had available cash and cash equivalents of $51.1 million. We believe that these funds, expected cash receipts primarily attributed to our collaboration with HEALIOS K.K. (“Healios”) and proceeds from our equity facility 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 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 facility, 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.
Reclassifications
Certain reclassifications have been made to the 2017 and 2016 consolidated financial statements to separately disclose transactions and balances related to Healios to conform to the 2018 presentation.
Revenue Recognition
Our license and collaboration agreements may contain multiple elements, including license and technology access fees, research and development funding, product supply revenue, service revenue, cost-sharing, milestones and royalties. As further described below, on January 1, 2018, we adopted Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (“Topic 606”), to account for revenue. The deliverables under our arrangements are evaluated under Topic 606 which 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.
Milestone Payments
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 are recognized based on an assessment of the probability of milestone achievement 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. Since the milestones in the Healios arrangement are generally related to development and commercial milestone achievement by Healios, we have not included any of the Healios milestones in the estimated transaction price of the Healios arrangement, since they would be constrained, as a significant reversal of revenue could result in future periods.
Other than for our collaboration with Healios that has remaining deliverables, as of the date of adoption of Topic 606 on January 1, 2018, we had recognized the full amount of license fees under our collaboration agreements as contract revenue under the prior guidance associated with multiple-element arrangements, since the performance periods for our multiple element arrangements had concluded. The events triggering any future contingent milestone payments from these arrangements were determined to be non-substantive and revenue will be recognized in the period that the triggering event occurs, and the remaining potential commercial milestones will be recognized when earned.

Table of Contents

Grant Revenue

Grant revenue, which is not within the scope of Topic 606 for our grant arrangements, 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 grant-funded activities are performed, with any advance funding recorded as deferred revenue until the activities are performed.

Royalty Revenue

We generate royalty revenue from the sale of licensed products by our licensees. Royalty revenue is recognized upon the later to occur of (i) achievement of the collaborator’s underlying sales and (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the license to our intellectual property is deemed to be the predominant item to which the sales-based royalties relate.

Unbilled Accounts Receivable

We record amounts that are due to us under contractual arrangements for which invoicing has not yet occurred if our performance has concluded for the billable activity, and we have the unconditional right to the consideration, but such amounts have not yet been billed. At December 31, 2018, unbilled accounts receivable from Healios was $3.6 million, which includes $2.5 million of license fees that were paid to us by Healios in the first quarter of 2019 related to the expansion of our arrangement described in Note E. The remainder of the unbilled accounts receivable on the consolidated balance sheets at December 31, 2018 relates to manufacturing technology transfer services performed that were not yet billed to Healios.

Contractual Right to Consideration and Deferred Revenue

Amounts included in deferred revenue or contract assets are determined at the contract level, and for our Healios arrangement, such amounts are included in a contract asset or liability depending on the overall status of the arrangement. Amounts received from customers or collaborators in advance of our performance of services or other deliverables are included in deferred revenue, while amounts for performance of services or other deliverables before customer payment is received or due are included in contract assets, with those amounts that are unconditional being included in either accounts receivable or unbilled accounts receivable. Grant proceeds received in advance of our performance under the grant is included in deferred revenue. Generally, deferred revenue and contract assets or liabilities are classified as current assets or obligations, as opposed to non-current.

Deposit from Healios

Included in the deposit from Healios at December 31, 2018 is a $2.0 million payment received from Healios to extend the period of its exclusive right to negotiate for an option to expand its license to develop and commercialize certain disease indications in China. These nonrefundable proceeds will either be applied to Healios' option fee for the China license or be creditable against potential milestone payments under the existing Healios licenses.

Advances from Healios

The clinical trial supply agreement with Healios was amended in July 2017 to clarify a cost-sharing arrangement associated with our supply of clinical product for Healios' ischemic stroke trial in Japan. The proceeds from Healios for clinical supply that relate specifically to the cost-sharing arrangement may (i) result in a decrease in the amount we receive from Healios upon the achievement of certain milestones and an increase to a commercial milestone, or (ii) be repaid at our election. While the amendment to the supply agreement resulted in a revision to the terms associated with the product supply, namely the cost of product supply, the revision did not affect any of the performance obligations under the overall arrangement. The proceeds from Healios that relate specifically to the cost-sharing arrangement for Healios’ ischemic stroke study in Japan are recognized as a non-current advance from Healios until the related milestones are achieved or such amounts are repaid to Healios at our election. No revenue has been recognized yet related to this advance.

Effect of Adoption of Topic 606

We adopted Topic 606 utilizing the modified retrospective transition method applied to contracts that were not complete as of January 1, 2018. We evaluated all of our arrangements on a contract-by-contract basis, identifying all of the performance obligations, including those that are contingent. For our contracts with customers that contain multiple performance obligations, we account for the individual performance obligations separately when they are

both capable of being distinct, whereby the customer can benefit from the service either on its own or together with other resources that are readily available from third parties or from us, and are distinct in the context of the contract, whereby the transfer of the services is separately identifiable from other promises in the contract. Under the new standard, we assessed whether licenses granted under our collaboration and license agreements were 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

Table of Contents

thereto, we recognized a cumulative effect adjustment of $1.9 million as an adjustment to the opening balance of our accumulated deficit primarily related to a contract asset 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 concluded that the new guidance resulted in revisions to accounting for our arrangement with Healios, only, since our other collaborations had no remaining performance obligations and potential contingent receipts would be constrained.

The adoption of ASC 606 primarily resulted in the acceleration of revenue as of December 31, 2017, which in turn reduced our existing deferred tax asset for net operating loss carryforwards. As we have provided a full valuation allowance against our deferred tax assets, this impact was offset by a corresponding reduction to the valuation allowance.

Our performance obligations and methods used for determining the relative selling prices and transaction prices of the Healios contract elements is further discussed in Note E.

As noted above, our arrangement with Healios was the only collaboration that was impacted by the adoption of Topic 606. Notes E and F further describe our arrangement with Healios, including subsequent modifications to the original collaboration. For contracts that were modified prior to January 1, 2018, we aggregated the effect of those modifications when identifying the satisfied and unsatisfied performance obligations and determining the transaction price to be allocated. We applied the practical expedient under Topic 606 and reflected the aggregate effect of all modifications at January 1, 2018. The components of the cumulative effect of the changes made to our consolidated January 1, 2018 balance sheet for the adoption of Topic 606 were as follows (in thousands):

	Balance at December 31, 2017	Adjustments Due to Topic 606	Balance at January 1, 2018
Assets			
Accounts receivable - Healios	$153	$ 30	$183
Contractual right to consideration from Healios	—	1,436	1,436
Liabilities			
Deferred revenue - Healios	(521)	521	—
Advance from Healios	(134)	(116)	(250)
Stockholders' Equity			
Accumulated deficit	$(350,630)	$ 1,871	$(348,759)

In accordance with the new revenue recognition requirements, the disclosure of the impact of adoption on our consolidated balance sheet as of December 31, 2018 and statement of operations for the twelve-month period ended December 31, 2018 was as follows (in thousands, except per share data):

	As of December 31, 2018		
	As Reported	Balances without Adoption of Topic 606	Effect of Change
Assets			
Unbilled accounts receivable from Healios	$3,620	$—	$3,620
Liabilities			
Deferred revenue - Healios	(674)	(2,154)	1,480
Stockholders' Equity			
Accumulated deficit	$(373,042)	$(378,142)	$(5,100)

60

Table of Contents

	Twelve months ended December 31, 2018		
	As Reported	Balances without Adoption of Topic 606	Effect of Change
Revenues			
Contract revenues from Healios	$22,276	$19,047	$3,229
Net loss	(24,283)	(27,512)	(3,229)
Net loss per common share			
Basic and diluted	$(0.18)	$(0.20)	$0.02

The adoption of Topic 606 had no impact on our total cash flows from operations.

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. 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 both 2018 and 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, if any, typically consist of United States government obligations, United States 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, 2018, we had no available-for-sale securities, and realized gains and losses for each of the three years in the period ended December 31, 2018 on available-for-sale securities were insignificant.

Research and Development

Research and development expenditures, which consist primarily of costs associated with clinical trials, preclinical research, product manufacturing and process development for manufacturing, personnel, legal fees 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.

Clinical Trial Costs

Clinical trial costs are accrued based on work performed by outside contractors that manage and perform the trials, and those that manufacture the investigational product. We obtain initial estimates of total costs based on enrollment of subjects, trial duration, project management estimates, manufacturing estimates, patient treatment costs and other activities. Actual costs may be charged to us and recognized as the tasks are completed by the contractor or, alternatively, may be invoiced in accordance with agreed-upon payment schedules and recognized based on 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.

Royalty Payments and Sublicense Fees

We are required to make royalty payments to certain parties based on our product sales under license agreements. No royalties were recorded during the three-year period ended December 31, 2018, since we have not yet generated sales revenue. We are also required to record sublicense fees from time-to-time in connection with license fees from

collaborators and clinical and commercial milestone achievement, of which $0.6 million and $0.3 million were recorded as research and development expenses in the Consolidated Statements of Operations in the years ended December 31, 2018 and 2016, respectively.

Table of Contents

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, and we recognized a net insurance recovery gain of $0.7 million in 2016 that was reported as a separate component of our loss from operations. An additional $0.6 million of insurance proceeds, net of associated expenses, were received in 2018, concluding the insurance claim. 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.

Patent Costs and Rights

Costs of applying for, 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.

Warrants

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. We had no warrant liabilities at December 31, 2018 and 2017, since certain warrants that were classified as liabilities expired during 2017. Refer to Note F for a warrant issued in 2018 to Healios (the “Healios Warrant”), which is accounted for as an equity instrument.

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, 2018, the majority of our accounts receivable are due from Healios. We do not typically require collateral from our 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.

62

Table of Contents

We recognize income tax benefits and deficiencies as income tax expense or benefit in the consolidated statement of operations 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 the consolidated statement of cash flows. In regards to forfeitures, we account for them when they occur following the adoption of ASU 2016-09, Compensation - Stock Compensation - Improvements to Employee Share-Based Payment Accounting, in 2017.

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.

Annual stock-based awards to employees typically vest over a four-year period, although the 2018 awards vest over a three-year period, have an exercise price equal to the fair market value of a share of common stock on the grant date and have a contractual term of 10 years. The following weighted-average input assumptions were used in determining the fair value of the Company's stock options:

	December 31,		
	2018	2017	2016
Volatility	70.8 %	71.2 %	70.3 %
Risk-free interest rate	2.8 %	2.0 %	1.5 %
Expected life of option	6.0 years	6.2 years	6.2 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, 2018 and 2017. 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 warrants, we evaluate the income from such warrant liabilities and consider whether it results in a potentially dilutive effect to net loss per share. There were no such dilutive effects from warrant liabilities for each of the periods ended December 31, 2018, 2017 and 2016.

We have outstanding options, restricted stock units and 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:

	Years ended December 31,		
	2018	2017	2016
Stock options	10,955,508	8,919,113	9,236,228
Restricted stock units	1,656,688	1,648,986	1,201,159
Warrants, including Healios Warrant	18,500,000	—	1,893,527
	31,112,196	10,568,099	12,330,914

Recently Issued Accounting Standards

In August 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-15, Intangibles-Goodwill and Other-Internal-Use Software: Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract ("ASU 2018-15"). ASU 2018-15 requires implementation costs incurred by

customers in cloud computing arrangements (i.e., hosting arrangements) to be capitalized under the same premises of authoritative guidance for internal-use software and deferred over the noncancellable term of the cloud computing arrangements plus any option renewal periods that

Table of Contents

are reasonably certain to be exercised by the customer or for which the exercise is controlled by the service provider. The guidance is effective for the annual and interim periods beginning after December 15, 2019, with early adoption permitted. We have outstanding cloud computing arrangements and continue to incur costs that we believe may be required to be capitalized under ASU 2018-15, including those related to our 2018 implementation of a new enterprise resource planning system. We are currently evaluating the potential impact of adoption of this standard on our consolidated financial statements and we do not intend to early adopt.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurements ("Topic 820"): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement, which adds, modifies and removes several disclosure requirements relative to the three levels of inputs used to measure fair value in accordance with Topic 820, Fair Value Measurement. This guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted. We are currently assessing the effect that this ASU will have on our disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases ("Topic 842"), which requires lessees to put most leases with a term greater than 12 months on their balance sheets, but recognize expenses on their statement of operations 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. We adopted Topic 842 effective January 1, 2019. We will elect the 'package of practical expedients' and will not reassess our prior conclusions about lease identification, lease classification and initial direct costs. We will also elect the short-term lease recognition exemption for all leases that qualify and will not recognize right-of-use assets or lease liabilities for those leases. Based on contracts in place at December 31, 2018, we expect our ROU asset and lease liability recorded will be approximately 2% of our total assets and do not expect the standard to have a material effect on our cash flows or results of operations.

In June 2018, the FASB issued ASU 2018-07, Compensation - Stock Compensation ("Topic 718"), Improvements to Nonemployee Share-Based Payment Accounting. This aligns the measurement and classification guidance for share-based payments to nonemployees with that for employees, with certain exceptions. It also expands the scope of Topic 718 to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in the entity's own operations. We have elected to early adopt this guidance which did not materially impact our consolidated financial statements.

In August 2018, the Securities and Exchange Commission ("SEC") issued the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, that amends certain of its disclosure requirements that have become redundant, duplicative, overlapping, outdated or superseded. The amendments include replacing the requirement to disclose the high and low trading prices of entity's ordinary shares with a requirement to disclose the ticker symbol of its shares. Additionally, the final rule extends to interim periods the annual disclosure requirement of presenting changes in each caption of stockholders' equity and the amount of dividends per share. These disclosures are required to be provided for the current and comparative year-to-date interim periods. We have adopted all relevant disclosure requirements in our annual report on Form 10-K for the year ended December 31, 2018.

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements ("Topic 808"): Clarifying the Interaction between Topic 808 and Topic 606. The amendments in this update make targeted improvements to generally accepted accounting principles ("GAAP") for collaborative arrangements as follows: clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements; add unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606; and require that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is

precluded if the collaborative arrangement participant is not a customer. The provisions of ASU 2018-18 are effective for years beginning after December 15, 2019, with early adoption permitted. We are currently evaluating the impact of this clarifying guidance.

Table of Contents

C. Equipment

	December 31,	
Equipment consists of (in thousands):	2018	2017
Laboratory equipment	$7,444	$6,262
Office equipment and leasehold improvements	3,043	3,039
Process development equipment not yet in service	822	363
	11,309	9,664
Accumulated depreciation	(8,307)	(7,458)
	$3,002	$2,206

In 2017, we disposed of approximately $0.8 million 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, 2018, we had no financial assets or liabilities measured at fair value on a recurring basis. The Healios Warrant that was issued in March 2018 was measured at fair value on a nonrecurring basis and is a Level 3 equity instrument under the hierarchy. Refer to Note F regarding its valuation.

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 2021, with options to renew annually through March 2024. Our rent is $267,000 per year and our rental rate has not changed since the lease inception in 2000. We also lease office and laboratory space for our Belgian subsidiary, which expires in July 2020 (we renewed the lease for an additional term in March 2019). This lease includes options to renew annually through July 2022 and annual rent expense is approximately $196,000, subject to adjustments based on an inflationary index. Rent expense is recognized on a straight-line basis over the minimum lease term.

Aggregate rent expense was approximately $493,000, $477,000 and $465,000 in 2018, 2017 and 2016, respectively. The future annual minimum lease commitments at December 31, 2018 are approximately $393,000 for 2019, $297,000 for 2020, and $90,000 for 2021. Refer to Note B regarding our adoption of ASU 2016-02 in January 2019 to account for our leases.

We paid no interest during the three years ended December 31, 2018.

Table of Contents

E. Collaborative Arrangements and Revenue Recognition

Healios Collaboration

In 2016, we entered into a license agreement (the “First 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 MAPC technology for use in Healios' “organ bud” program, initially for transplantation to treat liver disease or dysfunction. Under the terms of the First License 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 at that time included acute respiratory distress syndrome (“ARDS”) and another indication in the orthopedic area, and all indications for the “organ bud” program. In accordance with the First License Agreement, in addition to potential royalties and milestones, we received a nonrefundable up-front cash payment of $15 million, and if expanded at Healios’ election, Healios would pay an additional $10 million cash payment. Healios exercised its option to expand the collaboration in June 2018, as described below.

Under the collaboration, Healios is responsible for the development and commercialization of the MultiStem product in the licensed territories, and we provide manufacturing services to Healios, currently comprising the supply of product for its clinical trials and the transfer of technology to a contract manufacturer in Japan to produce product for Healios. We receive payments for these products and services provided to Healios.

In 2017, we signed a clinical trial supply agreement for delivering the planned manufacturing services for Healios’ clinical trial in Japan treating ischemic stroke patients. The clinical trial supply agreement was amended later that year to clarify the operational elements, terms and cost-sharing arrangement associated with our supply of clinical material and certain adjustments to potential milestone payments related to the clinical product supply for Healios’ TREASURE study in Japan. Healios’ cost-share payments may be creditable against milestone payments that may become due under the First License Agreement and a sales milestone would be increased, or such payments may be repaid by us at our election. Services to Healios under the clinical trial supply agreement are ongoing.

Also in 2017, we entered into a technology transfer services agreement with Healios, in which Healios provides financial support to establish a contract manufacturer in Japan to produce product for Healios. At that time, we also amended the First License Agreement to confer to Healios a limited license to manufacture MultiStem in the event that we are acquired by a third-party. Services to Healios under the technology transfer services agreement are ongoing.

In March 2018, we entered into a letter of intent (“LOI”), with Healios outlining the terms for a potential expansion of the relationship with Healios beyond that contemplated by the First License Agreement, to include, among other things, the exercise of its option to license the ARDS field in Japan and organ buds for all organ diseases, a worldwide exclusive license for use of MultiStem product to treat certain ophthalmological indications, and an exclusive option to a license to develop and commercialize certain MultiStem treatments in China. In connection with the LOI, in March 2018, Healios purchased 12,000,000 shares of our common stock and the Healios Warrant for $21.1 million, or approximately $1.76 per share.

In June 2018, Healios exercised its option to expand the collaboration to include ARDS and expand organ bud as contemplated by the First License Agreement, and entered into the Collaboration Expansion Agreement (“CEA”) that included new license agreements and rights that further broadened the collaboration. Under the CEA, Healios (i) expanded its First License Agreement to include ARDS in Japan, expanded the organ bud license to include all transplantation indications, and terminated Healios’ right to include a designated orthopedic indication per the First License Agreement; (ii) obtained a worldwide exclusive license, or the Ophthalmology License Agreement, for use of MultiStem product to treat certain ophthalmological indications; (iii) obtained an exclusive license in Japan (“the Combination Product License Agreement”), for use of the MultiStem product to treat diseases of the liver, kidney, pancreas and intestinal tissue through local administration of MultiStem in combination with iPSC-derived cells; (iv) obtained an exclusive, time-limited right of first negotiation (“ROFN Period”) to enter into an option for a license to develop and commercialize certain MultiStem treatments in China; and (v) an option for an additional non-therapeutic technology license. For all indications, Healios is responsible for the costs of clinical development in its licensed territories, and we provide manufacturing services to Healios.

For the rights granted to Healios under the CEA, Healios paid us a nonrefundable, up-front cash payment of $10.0 million to exercise its option to license ARDS and expand its license for organ bud, as contemplated by the First License Agreement, and paid an additional $10.0 million for the new license rights, which has been paid in full in four quarterly installment payments of $2.5 million. The payments were received in the second, third and fourth quarters of 2018 with the final payment received in the first quarter of 2019. Healios may elect to credit up to $10.0 million against milestone payments that may become due under the First License Agreement, as expanded to include ARDS, with limitations on amounts that may be credited to earlier milestone payments versus later milestone payments.

Table of Contents

For each of the ischemic stroke indication and the ARDS indication, we may receive success-based regulatory filing and approval and sales milestones aggregating up to $225 million in aggregate for each indication, subject to potential milestone credits. Milestone payments are non-refundable and non-creditable towards future royalties or any other payment due from Healios. We may 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.

For standalone products sold by Healios under the Ophthalmology License Agreement, we are entitled to receive success-based regulatory filing and approval and sales milestones aggregating up to $135.6 million and tiered royalties on net product sales in the single digits depending on net sales levels. For the combination products under the Ophthalmology License Agreement, we will be entitled to receive a low single-digit royalty, but no milestone payments. Under the Combination Product License Agreement, we are entitled to receive a low single-digit royalty on net sales of the combination product treatments, but no milestone payments. For the “organ bud” product, we are entitled to receive a fractional royalty percentage on net sales of the “organ bud” products; and we have a time-limited right of first negotiation for commercialization of an “organ bud” product in North America.

Under the CEA, the ROFN Period with respect to the option for a license in China was initially to expire on September 1, 2018, but was extended to June 30, 2019 in exchange for a $2.0 million payment from Healios that we received in December 2018. Furthermore, Healios may make an additional payment of $3.0 million to extend the ROFN Period for another six months through December 31, 2019. All such extension payments would be creditable against the option fee payable by Healios upon execution of a China option agreement if entered into, or Healios may apply the extension payment amounts as credits against any potential milestone payments under the current licenses, subject to certain limitations.

In connection with the entry into the CEA, we amended the terms of the Healios Warrant as addressed in Note F.

Healios Revenue Recognition

At the inception of the Healios arrangement and again each time that the arrangement has been modified, all material performance obligations were identified, which include (i) licenses to our technology, (ii) product supply services, and (iii) services to transfer technology to a contract manufacturer on Healios’ behalf. It was determined that these performance obligations were both capable of being distinct and distinct within the context of the contract. We develop assumptions that require judgment to determine the standalone selling price in order to account for our collaborative agreements, as these assumptions typically include probabilities of obtaining marketing approval for the product candidates, estimated timing of commercialization, estimated future cash flows from potential product sales of our product candidates, estimating the cost and markup of providing product supply and technical services, and appropriate discount rates.

In order to determine the transaction price, in addition to the fixed payments, we estimate the amount of variable consideration utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract, and the estimates for variable consideration are reassessed each reporting period. We constrain, or reduce, the estimates of variable consideration if it is probable that a significant reversal of previously recognized revenue could occur throughout the life of the contract, and both the likelihood and magnitude of a potential reversal of revenue are taken into consideration.

At inception and upon each modification date, once the estimated transaction price is established, amounts are allocated to each separate performance obligation on a relative standalone selling price basis. These performance obligations include any remaining, undelivered elements at the time of modifications and any new elements from a modification to the arrangement if the conditions are not met for being treated as a separate agreement. Following the June 2018 modification, the specific performance obligations that had been delivered included the licenses, and the performance obligations that were not yet fully delivered included clinical product manufacturing services and technology transfer services that we provide to a contract manufacturer in Japan. In the third quarter of 2018, an additional modification was executed to add clinical product manufacturing services for Healios’ planned ARDS study, which resulted in a new performance obligation, creating a modification to the arrangement and remeasurement of the transaction and standalone selling prices for the undelivered elements on the modification date.

For performance obligations satisfied over time, we apply an appropriate method of measuring progress each reporting period and, if necessary, adjust the estimates of performance and the related revenue recognition. Our

technology transfer services are satisfied over time, and we recognize revenue in proportion to the contractual services provided. For performance obligations satisfied at a point in time (i.e., product supply), we recognize revenue upon delivery.

The remaining transaction price for the performance obligations that were not yet delivered amounted to $3.6 million at December 31, 2018, which is expected to be recognized within one year as the goods and services are delivered. At December 31, 2018, the contract liability included in deferred revenue - Healios on the consolidated balance sheets, is properly classified as a current liability since the rights to consideration are expected to be satisfied, in all material respects, within one year.

Table of Contents

We included as a reduction of the transaction price of the licenses granted in the June 2018 expansion, the value of a portion of the Healios Warrant that was issued in March 2018 in connection with the then-proposed expansion under a letter of intent. Under the agreements in the June 2018 expansion that included an amendment to the Healios Warrant, 4,000,000 shares ("Warrant Shares") became exercisable, and as a result, $1.1 million of the $5.3 million initial warrant valuation was recorded in June 2018 as a reduction of revenue. In accordance with the June 2018 amendment to the Healios Warrant, the remaining 16,000,000 shares would not be exercisable until the execution of an option for a license in China, and the remaining $4.2 million of the Healios Warrant was reversed against additional paid-in-capital. See Note F.

Also, see Note B regarding our revenue recognition policies.

Advance from Healios

In 2017, we amended the clinical trial supply agreement for the manufacturing of investigational product for Healios for its Japan stroke clinical study to clarify a cost-sharing arrangement. The proceeds from Healios that relate specifically to the cost-sharing arrangement may either (i) result in a reduction in the proceeds we receive from Healios upon the achievement of two potential milestones and an increase to a commercial milestone under the First License Agreement for stroke, or (ii) be repaid to Healios at our election, as defined. The cost-sharing proceeds received are recognized on the balance sheet as a non-current advance from customer until the related milestone is achieved, unless 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.

Other Collaborators

Under our agreement with RTI Surgical, Inc. ("RTI") to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market, we have been receiving royalties on worldwide commercial sales of implants using our technologies and cash payments upon the achievement of certain commercial milestones. No milestone revenues have been received in 2018, and we received a commercial milestone payment of $1.0 million in 2017. However, RTI has announced that it will cease distribution of its bone graft product that utilizes our technology, and we expect royalty proceeds to cease.

In 2017, we received a $0.3 million option fee from an animal health company in exchange for an exclusive period to evaluate our technology with an option to negotiate for a license to the technology for an animal health area. The nonrefundable option fee was initially recorded as deferred revenue and was recognized in the second quarter of 2018 as the agreement had expired.

Disaggregation of Revenues

We recognize license-related amounts, including upfront payments, exclusivity fees, additional disease indication fees, and development, regulatory and sales-based milestones, at a point in time when earned. Similarly, product supply revenue is recognized at a point in time, while service revenue is recognized when earned over time. The following table presents our contract revenues disaggregated by timing of revenue recognition and excludes royalty revenue (in thousands):

	Twelve months ended December 31, 2018	
	Point in Time	Over Time
Contract revenue from Healios:		
License fee revenue	$17,682	$—
Product supply revenue	1,445	—
Service revenue	—	3,149
Other contract revenue	251	—
Total disaggregated revenues	$19,378	$3,149

68

Table of Contents

F. Capitalization and Warrant Instruments

Capitalization

At December 31, 2018 and December 31, 2017, we had 300 million shares of common stock and 10.0 million shares of undesignated preferred stock authorized. No shares of preferred stock have been issued as of December 31, 2018. 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, in thousands, of common stock were reserved for future issuance:

	December 31	
	2018	2017
Stock-based compensation plans	16,096	16,952
Healios Warrants to purchase common stock	18,500	—
Shares issuable upon patent milestone	—	500
	34,596	17,452

Proceeds from warrant exercises were $1.9 million and $0.2 million in 2017 and 2016, respectively.

Equity Issuance - Healios

In March 2018, Healios purchased 12,000,000 shares of our common stock for $21.1 million, or approximately $1.76 per share, and the Healios Warrant to purchase up to an additional 20,000,000 shares. In connection with this investment, we entered into an Investor Rights Agreement that governs certain rights of Healios and us relating to Healios' ownership of our common stock. The Investor Rights Agreement provides for customary standstill and voting obligations, transfer restrictions and registration rights for Healios. Additionally, we agree to provide notice to Healios of certain equity issuances and to allow Healios to participate in certain issuances in order maintain its proportionate ownership of our common stock as of the time of such issuance. We further agreed that during such time as Healios beneficially owns more than 5.0% but less than 15.0% of our outstanding common stock, our Board of Directors (the "Board") will nominate a Healios nominee suitable to us to become a member of the Board, and during such time as Healios beneficially owns 15.0% or more of our outstanding common stock, our Board will nominate two suitable Healios nominees to become members of the Board, at each annual election of directors. Healios nominated an individual to the Board, who was elected at the 2018 annual stockholders' meeting. As a result of Healios' investment, Healios became a related party, and the transactions with Healios are separately identified within these financial statements as related party transactions.

The value of the Healios Warrant was considered as an element of compensation in the transaction price of the Healios collaboration expansion. The Healios Warrant originally would not become effective until the expansion as contemplated under the LOI became effective in June 2018 and the first payment was made under the expansion. Upon entering into the CEA, the Healios Warrant became exercisable with respect to 4,000,000 Warrant Shares. These Warrant Shares are exercisable at the greater of $1.76 and the Reference Price (which is generally 110% of the average closing price per share of the Company's common stock for the ten trading days ending on the trading day immediately preceding the date the Warrant is exercised). The remaining 16,000,000 shares underlying the Healios Warrant will become exercisable only if Healios agrees to execute an option for a license in China. As of December 31, 2018, 1,500,000 of the 16,000,000 shares underlying the Healios Warrant will no longer be exercisable according to the terms of the Healios Warrant. Other Healios Warrant terms include a general expiration date in September 2020, as defined, fixed and floating exercise price mechanisms, and an exercise cap triggered at Healios' ownership of 19.9% of our common stock. The Healios Warrant may be terminated by us under certain conditions.

We evaluated the various terms of the Healios Warrant and concluded that it is accounted for as an equity instrument at inception and $5.3 million was computed as the best estimate of the fair value of the Healios Warrant at the time of issuance in March 2018. The fair value was computed using a Monte Carlo simulation model that included probability-weighted estimates of potential milestone points in time that could impact the value of the Healios Warrant during its term. The fair value was recorded as additional paid-in capital in the first quarter of 2018, with the offset being included in other asset related to Healios, and the asset would be included as an element of compensation in the transaction price upon the expansion proposed in March 2018 under the LOI.

Upon the modification of the Healios Warrant in June 2018 in connection with the expansion of the collaboration, we reassessed the fair value of the Healios Warrant immediately before and after the modification using the same valuation methodology providing for no incremental fair value to be recorded. The value of the 4,000,000 tranche of Warrant Shares that

Table of Contents

became effective upon the June 2018 expansion of $1.1 million was recorded as a reduction to the revenue recognized for the delivered licenses in June 2018. See Note E. However, since the June 2018 expansion agreements made the 16,000,000 shares underlying the Healios Warrant contingent on entering into an option for a license in China, we considered the ability to apply the $4.2 million value of such warrant shares as an element of compensation to be constrained. Therefore, the remaining asset was reversed against additional paid-in-capital.

Equity Purchase Agreement

We have had equity purchase agreements in place since 2011 with Aspire Capital Fund LLC ("Aspire Capital") that provide us the ability to sell shares to Aspire Capital from time to time, as appropriate. The current 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 this 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, 2018, 2017 and 2016, we sold 8,708,582, 9,400,000, and 2,191,418 shares, respectively, to Aspire Capital at average prices of $1.78, $1.75 and $1.84 per share, respectively. As of February 28, 2019, we had approximately 18.1 million shares remaining to sell to Aspire Capital under the 2018 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. Upon execution of the license and settlement agreement in 2017, we paid $0.5 million and issued 1,000,000 shares of our common stock with a fair value of $2.3 million. In 2018, in accordance with the agreement, we paid an additional $1.0 million and we issued 500,000 additional shares of our common stock related to a patent issuance. This contingent obligation to issue 500,000 shares of common stock was originally recorded in accrued license fee expense on the consolidated balance sheets at December 31, 2017 at a fair value of $0.9 million. The actual issuance of the 500,000 shares in May 2018 was recorded at an actual fair value of $1.2 million, resulting in $0.3 million of additional paid-in-capital and research and development expense in 2018. 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. Our payment obligations are concluded.

G. Stock-Based Compensation

We have a long-term incentive plan ("LTIP") that has an aggregate of 20,035,000 authorized shares of common stock for awards to employees, directors and consultants. The LTIP provides for 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, 2018, a total of 5,120,464 shares (including 250,579 shares related to an expired incentive plan) of common stock have been issued under our equity incentive plans.

As of December 31, 2018, a total of 3,483,912 shares were available for issuance under our LTIP, and stock-based awards to purchase 12,612,196 shares (including 930,993 shares related to the expired incentive plan) of common stock were outstanding. We recognized $3.8 million, $3.0 million and $2.9 million of stock-based compensation expense in 2018, 2017 and 2016, respectively.

Stock Options

The weighted average fair value of options granted in 2018, 2017 and 2016 was $1.46, $0.95 and $1.35 per share, respectively. The total fair value of options vested during 2018, 2017 and 2016 was $2.5 million, $2.0 million and $1.7 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2018, 2017 and 2016 was not significant. At December 31, 2018, total unrecognized estimated compensation cost related to unvested stock options was approximately $5.3 million, which is expected to be recognized by the end of 2022 using the straight-line method. The weighted average contractual life of unvested options at December 31, 2018 was 8.7

years. The aggregate intrinsic value of fully vested option shares and option shares expected to vest as of December 31, 2018 was $0.2 million.

Table of Contents

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

	Number of Options	Weighted Average Exercise Price
Outstanding January 1, 2016	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
Granted	2,434,732	2.26
Exercised	(112,484)	1.57
Forfeited / Expired	(285,853)	2.62
Outstanding December 31, 2018	10,955,508	$ 1.87
Vested during 2018	2,045,058	$ 1.83
Vested and exercisable at December 31, 2018	6,630,228	$ 1.83

	December 31, 2018					
	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 – $1.71	5,634,994	6.7 years	$ 1.50	4,058,842	4.4 years	$ 1.52
$1.81 – $2.31	5,031,451	8.3 years	$ 2.19	2,287,573	3.4 years	$ 2.14
$2.45 – $5.28	289,063	2.1 years	$ 3.53	283,813	2.1 years	$ 3.55
	10,955,508			6,630,228		

Table of Contents

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, 2016	1,069,100	$ 1.55
Granted	933,552	2.19
Vested-common stock issued	(732,720)	1.71
Forfeited / Expired	(68,773)	1.90
Outstanding December 31, 2016	1,201,159	1.92
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
Granted	787,968	2.31
Vested-common stock issued	(741,424)	1.81
Forfeited / Expired	(38,842)	1.74
Outstanding December 31, 2018	1,656,688	$ 1.93
Vested/Issued cumulative at December 31, 2018	4,569,865	$ 1.73

The total fair value of restricted stock units vested during 2018, 2017 and 2016 was $1.3 million, $1.0 million and $1.3 million, respectively. At December 31, 2018, total unrecognized estimated compensation cost related to unvested restricted stock units was approximately $3.1 million, which is expected to be recognized by the end of 2021 using the straight-line method.

H. Income Taxes

At December 31, 2018, we had U.S. federal net operating loss and research and development tax credit carryforwards of approximately $151.4 million and $10.0 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 2032 and 2038. Additionally, as of December 31, 2018, we had federal net operating loss carryforwards generated after 2017 of $16.8 million that have an indefinite life, but with usage limited to 80% of taxable income in any given year. We also had foreign net operating loss carryforwards of approximately $21.6 million. Such foreign net operating loss carryforwards do not expire. We also had state and city net operating loss carryforwards aggregating approximately $65.5 million. Such state and city net operating loss carryforwards may be used to reduce future taxable income and tax liabilities and will expire at various dates between 2019 and 2038.

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”). We generated U.S. federal net operating loss carryforwards of $116.8 million, research and development tax credits of $10.0 million, and state and local net operating loss carryforwards of $65.3 million since 2012. We will update our analysis under Section 382 prior to using these attributes.

Table of Contents

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

	Percent of Income before Income Taxes	
	2018	2017
Statutory federal income tax rate	21.0 %	34.0 %
State income taxes - net of federal tax benefit	0.9 %	0.8 %
Other permanent differences	(3.7)%	(5.5)%
Valuation allowances	(29.2)%	24.1 %
Federal rate change	— %	(57.9)%
Research and development - U.S.	11.0 %	4.5 %
Research and development - Foreign	— %	— %
Effective tax rate for the year	— %	— %

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

	December 31,	
	2018	2017
Net operating loss carryforwards	$38,813	$35,409
Research and development credit carryforwards	9,979	7,301
Compensation expense	1,552	652
Other	1,166	1,467
Total deferred tax assets	51,510	44,829
Valuation allowance for deferred tax assets	(51,510)	(44,829)
Net deferred tax assets	$—	$—

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, 2018.

In December 2017, the U.S. federal government enacted legislation commonly referred to as the “Tax Cuts and Jobs Act” (the “TCJA”). The TCJA made 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 TCJA also eliminated alternative minimum tax and the 20-year carryforward limitation for net operating losses incurred after December 31, 2017, and imposes a limit on the usage of net operating losses incurred after such date equal to 80% of taxable income in any given year. The 80% usage limit will not have an economic impact on us until our current net operating losses are either utilized or expire. The carrying value of our deferred tax assets and liabilities is determined by the enacted U.S. corporate income tax rate. Consequently, any changes in the U.S. corporate income tax rate impacts the carrying value of our deferred tax assets and liabilities. 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. We have an overall foreign E&P deficit and accordingly have not recorded any Transition Tax obligation as of December 31, 2018.

As of December 31, 2018, we have completed the accounting for all the impacts of the TCJA. We continue to evaluate the impacts of the TCJA and will consider additional guidance from the U.S. Treasury Department, Internal Revenue Service or other standard-setting bodies. However, no additional adjustments were 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 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 $0.5 million, $0.3 million and $0.3 million in 2018, 2017 and 2016, respectively.

Table of Contents

J. Quarterly Financial Data (unaudited)

The following table presents quarterly data for the years ended December 31, 2018 and 2017, in thousands, except per share data:

	2018				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
Revenues (1)	$1,066	$19,391	$2,321	$1,513	$24,291
Income (loss) from operations	(10,262)	6,745	(9,976)	(11,552)	(25,045)
Net income (loss)	(10,155)	6,933	(9,740)	(11,321)	(24,283)
Basic and diluted net loss per common share	$(0.08)	$0.05	$(0.07)	$(0.08)	$(0.18)

	2017				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
Revenues (1)	$1,470	$669	$399	$1,170	$3,708
Loss from operations	(6,398)	(6,338)	(7,332)	(13,215)	(33,283)
Net loss	(5,631)	(6,267)	(7,243)	(13,100)	(32,241)
Basic and diluted net loss per common share (2)	$(0.06)	$(0.06)	$(0.06)	$(0.11)	$(0.29)

(1) We adopted Topic 606 effective January 1, 2018 as further described in Note B to the consolidated financial statements. As a result, the recognized revenue in 2018 is not accounted for on the same basis as the prior years and is not comparable largely due to the timing of revenue recognition.

(2) 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.

Table of Contents

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, 2018, 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, 2018. The effectiveness of our internal control over financial reporting as of December 31, 2018 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 2018, there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On January 11, 2019, 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, 2019 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, 2019 through December 31, 2019. 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 and manufacturing process development initiatives, 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 10.34 and is hereby incorporated herein by reference thereto.

Table of Contents

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 2019 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 2019 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, 2018, unless otherwise indicated.

Plan Category	Number of securities to be issued upon exercise of outstanding awards	Weighted-average exercise price of outstanding awards	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a) (1)	(b) (2)	(c) (1)
Equity compensation plan approved by security holders	10,024,515	$ 1.90	3,483,912
Equity compensation plan not approved by security holders (3)	930,993	$ 1.58	—
Total	10,955,508		3,483,912

(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 stock options only, as opposed to RSUs that do not have an exercise price. The weighted average exercise price of all outstanding stock option awards under our plans is $1.87 and the weighted average remaining term is 7.32 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 2019 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 2019 Annual Meeting of Stockholders.

Table of Contents

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, 2018 and 2017

Consolidated Statements of Operations and Comprehensive Loss for each of the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Stockholders' Equity for each of the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Cash Flow for each of the years ended December 31, 2018, 2017 and 2016

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, 2018					
Deducted from asset accounts:					
Tax valuation allowances	$ 44,829	$ 6,681	$ —	$ 51,510	(A)
Total 2018	$ 44,829	$ 6,681	$ —	$ 51,510	
Year Ended December 31, 2017					
Deducted from asset accounts:					
Allowance for doubtful accounts-note receivable	$ 376	$ —	$ (376)	$ 0	(B)
Tax valuation allowances	54,772	—	(9,943)	44,829	(A)
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	(B)
Tax valuation allowances	48,921	5,851	—	54,772	(A)
Total 2016	$ 49,284	$ 5,864	$ —	$ 55,148	

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

(B) – Reserve on note receivable that was fully-reserved. We wrote-off the note in 2017.

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.

Table of Contents

(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 and restated as of March 13, 2019 (incorporated herein by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on March 14, 2019)
4.1	Common Stock Purchase Warrant issued to HEALIOS K.K. by Athersys, Inc. dated March 14, 2018 (incorporated herein by reference to Exhibit 4.1 to the registrant's Quarterly Report on Form 10-Q (Commission 001-33876) filed with the Commission on May 10, 2018)
4.2	Amendment No. 1 to Common Stock Purchase Warrant issued to HEALIOS K.K. by Athersys, Inc. dated as of June 6, 2018 (incorporated herein by reference to Exhibit 4.1 to the registrants Quarterly Report on Form 10-Q (Commission No. 001-33876) filed with the Commission on August 9, 2018)
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)

Table of Contents

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)
10.18†	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)

Table of Contents

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†	Summary of Athersys, Inc. 2019 Cash Bonus Incentive Plan
10.35	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)
10.36	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)
10.37	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)
10.38	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)

10.39	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)
10.40	Security Purchase Agreement, by and between Athersys, Inc. and HEALIOS K.K., dated as of March 13, 2018 (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 10, 2018)
10.41	Investor Rights Agreement, by and between Athersys, Inc. and HEALIOS K.K., dated as of March 13, 2018 (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 May 10, 2018)
10.42 *	Collaboration Expansion Agreement, by and between Athersys, Inc. and HEALIOS K.K., dated as of June 6, 2018 (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 August 9, 2018)
10.43	Amendment No. 1 to Collaboration Expansion Agreement, by and between Athersys, Inc. and HEALIOS K.K., dated as of August 31, 2018 (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 6, 2018)
10.44	Amendment No. 2 to Collaboration Expansion Agreement, by and between Athersys, Inc. and HEALIOS K.K., dated as of December 6, 2018

Table of Contents

10.45	Amendment No. 3 to Collaboration Expansion Agreement, by and between Athersys, Inc. and HEALIOS K.K., dated as of December 14, 2018
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.

Table of Contents

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 14, 2019.

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 14, 2019
/s/ Laura K. Campbell Laura K. Campbell	Senior Vice President of Finance (Principal Financial Officer and Principal Accounting Officer)	March 14, 2019
* John J. Harrington	Executive Vice President, Chief Scientific Officer and Director	March 14, 2019
* Hardy TS Kagimoto	Director	March 14, 2019
* Lorin J. Randall	Director	March 14, 2019
* Jack L. Wyszomierski	Director	March 14, 2019
* Lee E. Babiss	Director	March 14, 2019
* Ismail Kola	Director	March 14, 2019

* 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

82