ATHERSYS, INC / NEW
Form 10-Q
May 10, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 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

Former name, former address and former fiscal year, if changed since last report: Not Applicable

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

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

Indicate by check mark 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. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer (do not check if a smaller reporting company) Smaller reporting company
Emerging growth company

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

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

The number of outstanding shares of the registrant s common stock, $0.001 par value, as of May 1, 2018 was 137,958,545.

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ATHERSYS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

Athersys, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	**$ 49,673**	$ 29,316
Accounts receivable	**759**	586
Accounts receivable from Healios	**132**	153
Prepaid expenses and other	**1,020**	1,135
Contractual right to consideration from Healios	**1,538**	
Other asset related to Healios	**5,300**	
Total current assets	**58,422**	31,190
Equipment, net	**2,312**	2,206
Other	**200**	197
Total assets	**$ 60,934**	$ 33,593
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 8,092**	$ 4,469
Accrued compensation and related benefits	**743**	1,065
Accrued clinical trial costs	**430**	1,453
Accrued expenses	**389**	425
Accrued license fee expense	**1,665**	1,900
Deferred revenue	**250**	771
Total current liabilities	**11,569**	10,083
Advance from Healios	**1,833**	134
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at March 31, 2018 and December 31, 2017		
Common stock, $0.001 par value; 300,000,000 shares authorized, and 137,958,545 and 122,077,453 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	**138**	122

Additional paid-in capital	**406,308**	373,884
Accumulated deficit	**(358,914)**	(350,630)
Total stockholders equity	**47,532**	23,376
Total liabilities and stockholders equity	**$ 60,934**	$ 33,593

See accompanying notes to unaudited condensed consolidated financial statements.

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Athersys, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

	Three months ended March 31,	
	2018	**2017**
Revenues		
Contract revenue from Healios	**$ 348**	$ 28
Royalty and contract revenue	**401**	1,232
Grant revenue	**317**	210
Total revenues	**1,066**	1,470
Costs and expenses		
Research and development	**8,850**	5,633
General and administrative	**2,655**	2,071
Depreciation	**186**	164
Total costs and expenses	**11,691**	7,868
Gain from insurance proceeds	**363**	
Loss from operations	**(10,262)**	(6,398)
Income from change in fair value of warrants		728
Other income, net	**107**	39
Net loss and comprehensive loss	**$ (10,155)**	$ (5,631)
Net loss per common share, basic and diluted	**$ (0.08)**	$ (0.06)
Weighted average shares outstanding, basic and diluted	**126,897,425**	102,047,062

See accompanying notes to unaudited condensed consolidated financial statements.

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Athersys, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Three months ended March 31,	
	2018	**2017**
Operating activities		
Net loss	**$ (10,155)**	$ (5,631)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**186**	164
Stock-based compensation	**813**	689
Change in fair value of warrant liabilities		(728)
Changes in operating assets and liabilities:		
Accounts receivable	**(173)**	(1,168)
Accounts receivable from Healios	**(51)**	
Prepaid expenses and other	**127**	(231)
Accounts payable and accrued expenses	**1,992**	1,022
Advance from Healios	**1,583**	
Deferred revenue		503
Net cash used in operating activities	**(5,678)**	(5,380)
Investing activities		
Purchases of equipment	**(292)**	(134)
Net cash used in investing activities	**(292)**	(134)
Financing activities		
Proceeds from issuance of common stock, net	**26,411**	20,877
Shares retained for withholding tax payments on stock-based awards	**(84)**	(37)
Proceeds from exercise of warrants		1,861
Net cash provided by financing activities	**26,327**	22,701
Increase in cash and cash equivalents	**20,357**	17,187
Cash and cash equivalents at beginning of the period	**29,316**	14,753
Cash and cash equivalents at end of the period	**$ 49,673**	$ 31,940

See accompanying notes to unaudited condensed consolidated financial statements.

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Athersys, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Three-Month Periods Ended March 31, 2018 and 2017

1. Background and Basis of Presentation

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

We incurred losses since our inception in 1995 and had an accumulated deficit of $359 million at March 31, 2018. We will require substantial additional capital to continue our research and development programs, including progressing our clinical product candidates to commercialization and preparing for commercial-scale manufacturing. At March 31, 2018, we had available cash and cash equivalents of $49.7 million plus, under a proposed expansion to a collaboration discussed herein, our collaborator has funded $10 million as an expansion fee into an escrow account in March 2018 that is due to be released to us by June 1, 2018. We believe that these funds, used to execute our existing operating plans, are sufficient to meet our obligations as they come due at least for a period of twelve months from the date of the issuance of these unaudited condensed consolidated financial statements. In the longer term, we will make use of available cash, but will have to continue to generate additional capital to meet our needs through new and existing collaborations and related license fees and milestones, the sale of equity securities from time to time, including through our equity purchase agreement, grant-funding opportunities, deferring certain discretionary costs and staging certain development costs, as needed.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017. The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair presentation of financial position and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Our critical accounting policies, estimates and assumptions are described in Management s Discussion and Analysis of Financial Condition and Results of Operations, which is included below in this Quarterly Report on Form 10-Q.

2. Recently Issued Accounting Standards

In February 2016, the Financial Accounting Standards Board (FASB) issued ASU 2016-02, Leases (Topic 842), which requires lessees to put most leases on their balance sheets, but recognize expenses on their income statements in a manner similar to current accounting practice. Under the guidance, lessees initially recognize a lease liability for the obligation to make lease payments and a right-of-use (ROU) asset for the right to use the underlying asset for the lease term. The lease liability is measured at the present value of the lease payments over the lease term. The ROU asset is measured at the lease liability

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amount, adjusted for lease prepayments, lease incentives received and the lessee s initial direct costs. The guidance is effective for the annual and interim periods beginning after December 15, 2018, with early adoption permitted. We plan to adopt Topic 842 effective January 1, 2019 and are in the process of evaluating the impact the new guidance will have on our consolidated financial statements upon adoption. We currently have operating leases for two facilities that will need to be evaluated under this new guidance.

In May 2017, the FASB issued ASU 2017-09, Compensation Stock Compensation (Topic 718): Scope of Modification Accounting. This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The ASU is effective for the annual periods beginning after December 15, 2017 and interim periods within those annual periods. Effective January 1, 2018, we adopted this standard. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

3. Revenue Recognition and Adoption of New Accounting Pronouncement

Our license and collaboration agreements may contain multiple elements, including license and technology access fees, research and development funding, product supply revenue, cost-sharing, milestones and royalties. The deliverables under such an arrangement are evaluated under ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). Topic 606 requires an entity to recognize revenue in a manner that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, we apply the five steps under Topic 606 that an entity should apply when recognizing revenue.

We adopted this guidance as of January 1, 2018, utilizing the modified retrospective transition method applied to contracts that were not complete as of January 1, 2018. We evaluated all of our collaborative agreements on a contract-by-contract basis, identifying all of the performance obligations, including those that are contingent. 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 are distinct in the context of the agreement from other performance obligations and functional when granted. After considering the relative selling prices of the contract elements and the allocation of revenue thereto, we 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 also concluded that the new guidance resulted in revisions to accounting for our arrangement with Healios K.K. (Healios) only, since our other collaborations had no remaining performance obligations and potential contingent receipts would be constrained.

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 is recognized based on an assessment of the probability of

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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, 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 have concluded. The events triggering any future contingent milestone payments from these arrangements were determined to be non-substantive and revenue is recognized in the period that the triggering event occurs, and the remaining potential commercial milestones are recognized when earned.

Grant revenue

Grant revenue, which is not within the scope of Topic 606, 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.

Royalty Revenue

We recognize royalty revenue relating to the sale by a licensee of our licensed products. Royalty revenue is recognized upon the later to occur of (i) achievement of the collaborator s underlying sales or (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.

Deferred Revenue

Amounts received from customers or collaborators in advance of our performance of services or other deliverables is included in deferred revenue. For product supply, we typically invoice our customers a portion of the purchase order in advance, followed by invoices as product is released and available for pick-up. The amount paid in advance by the customer is applied to the last deliveries under the purchase order. Similarly, any grant proceeds received in advance of our performance under the grant is included in deferred revenue. Generally, deferred revenue is a current obligation, as opposed to non-current. During the three-month period ended March 31, 2018, we did not recognize any revenues that were deferred as of January 1, 2018.

Advance from Healios

As further described in Note 6, proceeds from Healios that relate specifically to the cost-sharing arrangement for Healios stroke study in Japan that may result in a net reduction in the proceeds we receive from Healios upon the achievement of future milestones are recognized as non-current advances from Healios until the related milestones are achieved or such amounts are repaid to Healios at our election. During the three-month period ended March 31, 2018, no revenue was recognized that was included in the advance from Healios as of January 1, 2018.

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Effect of Adoption of Topic 606

Our arrangement with Healios was the only collaboration that was impacted by the adoption of Topic 606. Notes 6 and 8 further describe our arrangement with Healios, including modifications that have resulted. We have applied the practical expedient under Topic 606 and have 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):

	As of December 31, 2017	Adjustments Due to Topic 606	As of 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)
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 condensed consolidated balance sheet and statement of operations for the three months ended March 31, 2018 was as follows (in thousands, except per share data):

	As Reported	As of March 31, 2018 Balances without Adoption of Topic 606	Effect of Change
Assets			
Contractual right to consideration from Healios	$ 1,538	$	$ 1,538
Liabilities			
Deferred revenue - Healios	$	$ (259)	$ 259
Equity			
Accumulated deficit	$ 358,914	$ 360,711	$ (1,797)

	Three months ended March 31, 2018		
	As Reported	Balances without Adoption of Topic 606	Effect of Change
Revenues			
Contract revenues - Healios	$ 348	$ 422	$ (74)
Net loss	$ (10,155)	$ (10,081)	$ 74
Net loss per common share			

Basic and diluted	$ (0.08)	$ (0.08)	$

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

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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 from Healios disaggregated by recognition at a point in time and over time (in thousands).

	Three months ended March 31, 2018		
	Recognized at Point in Time	Recognized Over Time	Total
Contract Revenues - Healios			
Product supply revenue	$ 227	$	227
Service revenue		121	121
Total	**$ 227**	**$ 121**	**$ 348**

4. 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. We have outstanding stock-based awards that are not used in the calculation of diluted net loss per share because to do so would be antidilutive. We have one warrant outstanding that was issued to Healios in March 2018, but Healios is not yet permitted to exercise any of the shares underlying the warrant. Refer to Note 8 for additional details. The following instruments were excluded from the calculation of diluted net loss per share because their effects would be antidilutive:

	Three months ended March 31,	
	2018	2017
Stock-based awards	**10,294,613**	10,091,837
Warrants see Note 8	**20,000,000**	
Total	**30,294,613**	10,091,837

5. Proceeds from Insurance

In 2016, our facility sustained flood damage representing both an unusual and infrequent event. Insurance proceeds are recorded to the extent of the losses and then, only if recovery is realized or probable. Any gains in excess of losses are recognized only when the contingencies regarding the recovery are resolved, and the amount is fixed or determinable. We recognized an insurance recovery gain of $0.4 million in the first quarter of 2018 as additional insurance proceeds were received.

6. Collaborative Arrangements and Revenue Recognition

Healios

2016 Inception of License Arrangement

In 2016, we entered into a license agreement (Healios Agreement) with Healios to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan and to provide Healios with access to our proprietary MAPC technology for use in its organ bud program, initially for transplantation to treat liver disease or dysfunction. Under the Healios Agreement, Healios obtained a right to expand the scope of the collaboration to include the exclusive rights to develop and commercialize MultiStem for the treatment of certain additional indications in Japan, which include acute respiratory distress syndrome (ARDS), and, as addressed herein, plans for an expansion of the collaboration are underway.

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Under the terms of the Healios Agreement, we received a nonrefundable, up-front cash payment of $15 million. Healios is responsible for the costs of clinical development in Japan. Athersys is providing manufacturing services to Healios, currently comprising the supply of product for its clinical trial and preparations for commercial manufacturing, and we receive payments for product supplied to Healios. We also receive financial support from Healios for services we perform to establish a contract manufacturer in Japan to produce product for Healios. The costs of the services are reimbursed by Healios at our cost.

For the ischemic stroke indication, we may also receive additional success-based development, regulatory approval and sales milestones, which are non-refundable and non-creditable towards future royalties or any other payment due from Healios. We 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.

If Healios exercised its option to expand the collaboration to include ARDS and another indication in the orthopedic area under the Healios Agreement, we would be entitled to receive a cash payment of $10 million at the time of exercise and royalties from product sales and success-based development, regulatory approval and sales milestones, as well as payments for product supply related to the additional indications covered by the option. Under the proposed expansion plans addressed herein, at a minimum, Healios would exercise its option to include the ARDS field under the Healios Agreement, and the $10 million expansion fee was funded by Healios into an escrow account in March 2018, which is due to be released to us by June 1, 2018. For the organ bud product, we are entitled to receive a fractional royalty percentage on net sales of the organ bud products and will receive payments for manufactured product supplied to Healios under a manufacturing supply agreement. Additionally, we have a right of first negotiation for commercialization of an organ bud product in North America, with such right expiring on certain dates in the future.

For the Healios arrangement, we identified all material performance obligations, which included a license to our technology, product supply services, and services related to transfer technology to a contract manufacture on Healios behalf. In order to determine the transaction price, in addition to the upfront payment, we estimated the amount of variable consideration at the outset of the contract utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. 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. Both the likelihood and magnitude of a potential reversal of revenue are taken into consideration. These estimates are re-assessed each reporting period, as necessary.

Once the estimated transaction price is established, amounts are allocated to the performance obligations that have been identified. The transaction price is allocated to each separate performance obligation on a relative standalone selling price basis. We must develop assumptions that require judgment to determine the relative standalone selling price in order to account for our collaborative agreements, as these assumptions typically include probabilities of obtaining marketing approval for our product candidates, estimated timing and cost of development and commercialization, estimated future cash flows from potential product sales of our product candidates, and appropriate discount and tax rates. We do not include a financing component to our estimated transaction price at contract inception unless we estimate that the performance obligations will not be satisfied within one year.

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We determined that the license in the Healios arrangement was distinct from the other performance obligations identified in the arrangement, and that the license was transferred to Healios and Healios was able to use and benefit from the license. Furthermore, the product supply services and the technology transfer services provided to Healios were also determined to be distinct. We then allocated the transaction price based on the relative value prescribed to the license compared to the overall arrangement. As a result of the analysis, we allocated to the license $17.3 million of the proceeds received and to be received in the future. 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. For our technology transfer services provided to Healios that are satisfied over time, we recognize revenue in proportion to the contractual services provided.

We computed the effect of the adoption of Topic 606, which is included in the cumulative effect adjustment as of January 1, 2018. Overall, the conclusions under the former guidance related to performance obligations, obligations being distinct within the contract and relative standalone selling prices did not change with the adoption of the new guidance. However, the transaction price was higher under Topic 606 since revenue recognition is no longer limited to cash proceeds received, and we were able to recognize more revenue for the delivered license. This additional revenue of $1.9 million was accounted for as a decrease to our accumulated deficit at January 1, 2018 and an increase to a contract asset and to a lesser extent, a decrease to deferred revenue. The contract asset was evaluated at March 31, 2018, noting that it is properly classified as a current asset since the conditional rights to consideration are expected to be satisfied within one year.

2017 Amendment Cost Share

In January 2017, we signed a clinical trial supply agreement for the manufacturing of investigational product for Healios for its Japan clinical study, the terms of which were consistent with the Healios Agreement. The clinical trial supply agreement was amended in July 2017 to clarify a cost-sharing arrangement associated with our supply of clinical product. The proceeds from Healios that relate specifically to the cost-sharing arrangement may result in a reduction in the proceeds we receive from Healios upon the achievement of two future milestones, and an increase to a later-stage commercial milestone. While the amendment to the supply agreement resulted in a revision to the terms associated with the product supply under the Healios Agreement, namely the cost of product supply, the revision did not affect any of the performance obligations under the overall arrangement. The cost-sharing proceeds received are recognized on the balance sheets as a non-current advance from Healios until the related milestone is achieved or such amounts are repaid to Healios at our election.

2017 Technology Transfer Services

In September 2017, we entered into a services agreement with Healios, in which Healios provides financial support to establish a contract manufacturer in Japan to produce product for Healios, and services began in the fourth quarter of 2017. We evaluated this agreement as combined with the Healios Agreement due to its connection to the license and the product supply under the Healios Agreement. The costs of the services, representing our performance obligation, are reimbursed by Healios at our cost. Given that Healios will benefit from the services as the services are performed, which is the intended purpose of the arrangement, we concluded that the services were distinct. We estimated the relative standalone value of the technology transfer services, which was included in the allocation of the transaction price for the overall Healios arrangement. The technology transfer services are recognized over time as the services are performed.

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

2018 Planned Expansion

In March 2018, we entered into a letter of intent (as amended in April 2018, the LOI) with Healios to significantly expand Healios license to develop MultiStem products and enter into a Collaboration Expansion Agreement (the Collaboration Expansion Agreement). Under the terms of the LOI, we and Healios will work to execute the agreements necessary to expand the existing collaboration by May 31, 2018. If the Collaboration Expansion Agreement is entered into in accordance with the terms of the LOI, Healios would (i) expand its license to include ARDS (including idiopathic pulmonary fibrosis) and trauma in Japan, and use of MultiStem worldwide for organ buds for all organ diseases, (ii) obtain a worldwide exclusive license for use of MultiStem product to treat certain ophthalmological indications, (iii) obtain an exclusive option to a license to develop and commercialize MultiStem products for ischemic stroke, ARDS and trauma in China, and (iv) obtain certain other rights. In exchange, if the Collaboration Expansion Agreement is entered into as contemplated by the LOI, we would be entitled to receive payments of $35 million ($10 million of which was funded in an escrow account to be paid to us upon execution), as well as additional possible payments, including milestones and royalties. Under the Collaboration Expansion Agreement, the remaining $25 million payment obligation would be paid in instalments that cannot be terminated over time, and though the payments would be non-refundable, they could be used as credits against certain milestone payments due under the license. If the Collaboration Expansion Agreement is entered into and thereafter Healios elects to exercise its option for the license in China, Healios would pay us license fees, milestone payments and escalating royalties or profit-sharing for each indication in China.

Under the binding terms of the LOI, we and Healios entered into an escrow agreement in March 2018, and Healios funded $10 million into the escrow account, which is to be paid to us no later than June 1, 2018 as either (i) a portion of the $35 million in payments associated with the execution of the Collaboration Expansion Agreement, or (ii) if Collaboration Expansion Agreement is not executed on or before May 31, 2018, payment for expanding the scope of the existing Healios Agreement to include ARDS and certain ophthalmological indications in Japan and use of MultiStem for organ buds for all organ diseases.

Also see Note 3 regarding our revenue recognition policies and Note 8 regarding the equity investment made by Healios in the first quarter of 2018 in connection with the planned expansion of the collaboration, and the issuance of a warrant to Healios.

Other

Under our agreement with RTI to develop and commercialize biologic implants using our technology for certain orthopedic applications in the bone graft substitutes market, we are eligible to receive up to $34.5 million in remaining cash payments upon the successful achievement of certain commercial milestones, after the first commercial milestone payment of $1.0 million was received in the first quarter of 2017. No milestone revenues were received in the first quarter of 2018. In addition, we receive tiered royalties on worldwide commercial sales of implants using our technologies based on a royalty rate starting in the mid-single digits and increasing into the mid-teens, and in the fourth quarter of 2017, the royalty rate increased into the low double-digits based on RTI s achievement of a second commercial milestone. Any royalties may be subject to a reduction if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product, and no such reductions were incurred in the first quarter of 2018 or 2017.

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In January 2017, we received an option fee related to an agreement with a global leader in the animal health business segment to evaluate our cell therapy technology for application in an animal health area. Under the terms of the agreement, we received the payment in exchange for an exclusive period to evaluate our cell therapy technology with an option to negotiate for a license for the development and commercialization of the technology for the animal health area. The option fee is recorded as deferred revenue at March 31, 2018 since the performance obligation of granting a license has not occurred. If the option is exercised, we will include the option fee in the overall consideration for the license arrangement, to be evaluated at that time. If the option is not exercised, the option fee will be recognized as revenue at that time since there will be no more performance obligations. The evaluation of our technology for this application is currently ongoing.

7. Stock-based Compensation

We have an incentive plan that authorized an aggregate of 20,035,000 shares of common stock for awards to employees, directors and consultants. The equity incentive plan authorizes the issuance of equity-based compensation in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units, and other stock-based awards. As of March 31, 2018, a total of 4,487,408 shares (including 241,652 shares related to an expired incentive plan) of common stock have been issued under our equity incentive plan.

As of March 31, 2018, a total of 6,435,880 shares were available for issuance under our equity compensation plan, and stock-based awards to purchase 10,294,613 shares (including 941,249 shares related to an expired incentive plan) of common stock were outstanding. For the three-month periods ended March 31, 2018 and 2017, stock-based compensation expense was approximately $813,000 and $689,000, respectively. At March 31, 2018, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately $6.5 million, which is expected to be recognized by the end of 2021 using the straight-line method.

8. Stockholders Equity

Equity Issuance - Healios

In March 2018, Healios purchased 12,000,000 shares of our common stock (the Shares) for $21,100,000, or approximately $1.76 per share, and a warrant (Warrant) to purchase up to an additional 20,000,000 shares of common stock (the Warrant Shares). In connection with the issuance of the Shares, we and Healios entered into an Investor Rights Agreement, which governs certain rights of Healios and us relating to Healios ownership of our common stock, including the Shares and the Warrant Shares. The Investor Rights Agreement provides for customary standstill and voting obligations, transfer restrictions and registration rights of 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 under the Investor Rights Agreement that during such time as Healios beneficially owns more than 5% but less than 15.0% of our outstanding common stock, our Board of Directors (the Board) will nominate one of Healios nominees 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 of Healios nominees suitable to us to become members of the Board, at each annual election of directors. Healios right to nominate an individual to the Board will not commence until the Collaboration Expansion Agreement has been entered into. As a result of Healios ownership position in us following its investment, Healios became a related party, and the transactions with Healios are separately identified within these financial statements as they are related party transactions.

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The Warrant does not become effective until the expansion agreements are effective, has a term that expires in September 2020 (subject to a potential extension), includes both fixed and floating exercise price mechanisms, and is capped such that in no event will Healios own more than 19.9% of our common stock. The Warrant may be terminated by us under certain conditions, including if Healios does not make the initial payment required by the Collaboration Expansion Agreement. We evaluated the various terms of the Warrant and concluded that it is appropriately accounted for as equity at inception and $5.3 million was computed as the best estimate of the fair value of the Warrant at the time of issuance. The fair value at inception 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 Warrant during its term. The fair value is recorded as additional paid-in capital in March 2018, with the offset included in other current assets.

Public Equity Offering

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

Equity Purchase Agreement

We have in place an equity purchase arrangement with Aspire Capital Fund LLC (Aspire Capital), which provides us the ability to sell shares to Aspire Capital from time-to-time, as appropriate. Our current arrangement with Aspire Capital that was entered into in February 2018 includes Aspire Capital s commitment to purchase up to an aggregate of $100 million of shares of common stock over a three-year period and 450,000 shares of common stock were issued as a commitment fee. We filed a registration statement for the resale of 24,700,000 shares of common stock in connection with the new equity facility. Furthermore, the prior facility that was entered into in December 2015 with Aspire Capital has approximately 2.0 million shares that remain available to us for issuance. During the quarter ended March 31, 2018, we sold 3,300,000 shares to Aspire Capital at an average price of $1.67 per share. We sold no shares to Aspire Capital in the first quarter of 2017.

License Agreement and Settlement

In October 2017, we entered into an agreement to settle longstanding intellectual property disagreements with a third party. As part of the agreement, we were granted a worldwide, non-exclusive license, with the right to sublicense, to the other party s patents and applications that were at the core of the intellectual property dispute, for use related to the treatment or prevention of disease or conditions using cells. In return, we agreed not to enforce our intellectual property rights against the party with respect to certain patent claims, nor to further challenge the patentability or validity of certain applications or patents. In connection with the license and settlement agreement, we paid $500,000 and issued 1,000,000 shares of our common stock with a fair value of $2.3 million upon execution of the agreement in 2017, and we are paying an additional $250,000 per quarter for four quarters. Additionally, we will issue 500,000 shares of common stock upon the issuance of a patent from the party s patent applications at the core of the dispute, which we deem to be probable. The contingent obligation to issue 500,000 shares of common stock, at fair value of $0.9 million and $0.9 million at March 31, 2018 and December 31, 2017, respectively, is included in accrued license fee expense on the condensed consolidated balance sheets.

9. 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.

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At March 31, 2018, we had no financial assets or liabilities measured at fair value on a recurring basis. At March 31, 2018, the Warrant was measured at fair value on a nonrecurring basis that represented a Level 3 equity instrument under the hierarchy. Refer to Note 8.

10. Income Taxes

We have U.S. federal net operating loss and research and development tax credit carryforwards, as well as state and city net operating loss carryforwards, which may be used to reduce future taxable income and tax liabilities. We also have foreign net operating loss and tax credit carryforwards, and the foreign net operating loss carryforwards do not expire. All of our deferred tax assets have been fully offset by a valuation allowance due to our cumulative losses.

The utilization of net operating loss and tax credit carryforwards generated prior to October 2012 is substantially limited under Section 382 of the Internal Revenue Code of 1986, as amended, as a result of our October 2012 equity offering. We generated U.S. federal net operating loss carryforwards, research and development tax credits, and state and local net operating loss carryforwards since 2012. We will update our analysis under Section 382 prior to using these attributes.

In December 2017, the U.S. federal government enacted legislation commonly referred to as the Tax Cuts and Jobs Act (the TCJA). The TCJA makes widespread changes to the IRC, including, among other items, a reduction in the federal corporate tax rate from 35% to 21%, effective January 1, 2018. The carrying value of our deferred tax assets and liabilities is also determined by the enacted U.S. corporate income tax rate. Consequently, any changes in the U.S. corporate income tax rate will impact the carrying value of our deferred tax assets and liabilities. Our deferred income tax assets, net, have provisionally decreased based on the reduction of the U.S. corporate tax rate and the valuation allowance has had a corresponding decrease. The Deemed Repatriation Transition Tax (Transition Tax) is a tax on previously untaxed accumulate 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 believe we have an overall foreign E&P deficit and, accordingly, have not recorded any provisional Transition Tax obligation. However, we are continuing to gather additional information to finalize our Transition Tax liability.

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We determined that the provisional calculations will be finalized after the underlying timing differences and foreign earnings and profits are finalized with our 2017 federal tax return filing. Furthermore, we are still analyzing certain aspects of the TCJA and refining our calculations which could potentially affect the measurement of these balances or potentially give rise to new or additional deferred tax amounts. We will consider additional guidance from the U.S. Treasury Department, IRS or other standard-setting bodies. Further adjustments, if any, will be recorded by us during the measurement period in 2018, as permitted by SEC Staff Accounting Bulletin 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act. No amounts were recorded as of March 31, 2018 for these potential adjustments.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

This discussion and analysis should be read in conjunction with our unaudited financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017. Operating results are not necessarily indicative of results that may occur in future periods.

Overview and Recent Developments

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

Current Programs

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

Ischemic Stroke: We are actively engaged in advancing the next stage of clinical development of this program, both independently and with Healios. We are currently preparing to launch our pivotal Phase 3 clinical trial of MultiStem cell therapy for the treatment of ischemic stroke, referred to as MASTERS-2. We intend to begin the study with specific high-enrolling sites, adding additional sites over time and as clinical product supply is available. The MASTERS-2 study has received several regulatory distinctions including Special Protocol Assessment, or SPA, Fast Track designation and the Regenerative Medicine Advanced Therapy designation, which was established under the 21st Century Cures Legislation, from the U.S. Food and Drug Administration, or FDA, as well as a Final Scientific Advice positive opinion from European Medicines Agency, or EMA.

Healios confirmatory clinical trial, TREASURE, evaluating the safety and efficacy of administration of MultiStem cell therapy for the treatment of ischemic stroke in Japan, is ongoing and continuing its enrollment. TREASURE will be evaluated under the recently established regulatory framework for regenerative medicine therapies in Japan.

Acute Respiratory Distress Syndrome, or ARDS: We have an ongoing Phase 1/2 clinical study for the treatment of ARDS in the United Kingdom and in the United States, and our objective is to complete this study in 2018. We were awarded a grant from Innovate UK as partial support of this clinical study, and such grant funding was concluded in the first quarter of 2018, according to its terms. We look forward to obtaining the study results.

Acute Myocardial Infarction, or 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 an AMI, but continue to enroll below expectations despite numerous efforts to improve the enrollment rates. The study had been

supported by a grant from the National Institutes of Health, which has now concluded. We will provide updates regarding the conduct and completion of the study, as appropriate.

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The University of Texas Health Science Center at Houston has announced plans recently 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 will be conducted at Memorial Hermann-Texas Medical Center, one of the busiest Level 1 trauma centers in the United States. The study will receive grant support of $2.0 million from the Medical Technology Enterprise Consortium and the Memorial Hermann Foundation will provide an additional $1.5 million. We will provide the clinical product for the conduct of the trial, as well as regulatory and operational support, as our contribution to the trial. The plans for this study are in the early stage, and we will provide further updates as preparations for the trial progress.

Hematopoietic Stem Cell Transplant / Graft-vs-Host Disease, or GvHD: Currently, this program is staged for future registration-directed development dependent on the achievement of certain business development and financial objectives and the development and success of alternative therapies for treating the underlying conditions leading to transplant. 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 hematopoietic stem cell 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 hematopoietic cell transplantation. Subsequently, our registration study design received a positive Scientific Advice opinion from 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. In January 2017, we entered into an evaluation and option agreement with a global leader in the animal health business segment to evaluate our cell therapy technology for application in an undisclosed animal health area, and such evaluation is ongoing.

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

In January 2016, we entered into a license agreement with Healios K.K., or Healios, to develop and commercialize MultiStem cell therapy for ischemic stroke in Japan, and to provide Healios with access to our proprietary technologies for use in Healios proprietary organ bud program. Healios is working toward the development and commercialization of the MultiStem product in Japan, and we are providing the manufactured product to Healios for its clinical studies; provided, that, if we fail to perform our responsibilities to supply clinical trial product to Healios, then under certain circumstances, we may be required to grant Healios a license to make the product solely for use in the licensed field in Japan. Under the agreement, Healios also obtained a right to expand the scope of the collaboration to include the exclusive rights to develop and commercialize MultiStem for the treatment of certain additional indications in Japan, including ARDS.

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In March 2018, we entered into a letter of intent, or LOI, as amended in April 2018, with Healios to expand Healios license to develop MultiStem products and are working to execute the necessary agreements by May 31, 2018. If the expansion is consummated as contemplated by the LOI, Healios would, among other things, (i) expand its license in Japan to include ARDS (including idiopathic pulmonary fibrosis) and trauma in Japan, and use of MultiStem worldwide for organ buds for all organ diseases, (ii) obtain a worldwide exclusive license for use of MultiStem product to treat certain ophthalmological indications, and (iii) obtain an exclusive option to a license to develop and commercialize MultiStem products for ischemic stroke, ARDS and trauma in China. In exchange, if the expansion as contemplated by the LOI is consummated, we would be entitled to receive payments of $35 million ($10 million of which is funded in an escrow account to be paid to us upon execution), as well as additional possible payments, including milestones and royalties, including for the license in China if Healios elects to exercise the proposed option for the license in China.

We also have a collaboration with RTI for the development of products for certain orthopedic applications using our stem cell technologies in the bone graft substitutes market, and we continue to receive royalty revenue from product sales and may receive other payments from time to time upon the successful achievement of certain commercial milestones. In 2017, we received a $1.0 million payment associated with achievement of a commercial milestone. Also, in the fourth quarter of 2017, our royalty rate increased as a result of reaching a milestone for product sales. No milestones were achieved in the first quarter of 2018.

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

Financial

As addressed herein, if the expansion of our collaboration with Healios is concluded as contemplated under the LOI, we expect to receive, at a minimum, the $10 million license fee that has been funded by Healios into an escrow account. If the full expansion is consummated, the LOI provides that we would be entitled to receive additional payments of $25 million, as well as additional possible payments such as milestones and royalties.

For the ischemic stroke indication under the existing 2016 license with Healios, we may receive additional success-based development, regulatory approval and sales milestones of $225 million in aggregate, subject to certain potential milestone credits, and tiered royalties on product sales that start in the low double digits and increase incrementally into the high teens depending on net sales levels. Additionally, we receive payments for product supplied to Healios under a manufacturing supply agreement, which is initially focused on clinical product supply, and, in 2017, we agreed to a cost-sharing arrangement with Healios for clinical product for its TREASURE trial in Japan that may impact the amount of proceeds we receive from future milestones. We began receiving cost-sharing proceeds late in 2017, and product supply is ongoing.

In addition, in September 2017, we entered into a services agreement with Healios, in which Healios provides financial support to establish a contract manufacturer in Japan to produce product for Healios, and services began in the fourth quarter of 2017. The costs of the services are reimbursed by Healios.

In connection with the entry into the LOI, Healios purchased 12,000,000 shares of our common stock for $21,100,000, or approximately $1.76 per share, and a warrant, or Warrant, to purchase up to an additional 20,000,000 shares of common stock. The Warrant will become exercisable once Healios makes the initial payment under the planned expansion under the LOI, except with respect to 4,000,000 shares underlying the Warrant that would become exercisable prior to such time upon release of the $10 million that has been funded into escrow, depending on the scope of the expansion. The Warrant may be terminated by us under certain conditions, including if Healios does not

make its required expansion payments.

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We have in place an equity purchase arrangement with Aspire Capital Fund LLC, or Aspire Capital, which provides us the ability to sell shares to Aspire Capital from time-to-time, as appropriate. Our current arrangement with Aspire Capital that was entered into in February 2018 includes Aspire Capital s commitment to purchase up to an aggregate of $100 million of shares of common stock over a three-year period and 450,000 shares of common stock were issued as a commitment fee. We filed a registration statement for the resale of 24,700,000 shares of common stock in connection with the new equity facility. Furthermore, the prior facility that was entered into in December 2015 with Aspire Capital has approximately 2.0 million shares that remain available to us for issuance. During the quarter ended March 31, 2018, we sold 3,300,000 shares to Aspire Capital at an average price of $1.67 per share. We sold no shares to Aspire Capital in the first quarter of 2017.

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 Warrant outstanding at March 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. In February 2018, we received an additional $0.4 million in insurance proceeds.

Results of Operations

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

Three Months Ended March 31, 2018 and 2017

Revenues decreased to $1.1 million for the three months ended March 31, 2018 compared to $1.5 million for the three months ended March 31, 2017. Our revenues are comprised of manufacturing-related activities for Healios, royalty and related contract revenue from our collaboration with RTI Surgical, Inc. and grant revenue. Our revenue from Healios increased during the first quarter of 2018 compared to the prior year first quarter by approximately $0.3 million as we continue to supply clinical product to Healios and provide other manufacturing-related services, and we expect these revenues will be higher for the 2018 annual period as compared to the 2017 year. Regarding our royalty revenue, excluding a $1.0 million milestone payment from RTI in the 2017 first quarter, royalty revenues increased in the first quarter of 2018 as a result of an increase in the royalty rate that became effective late 2017 associated with our technology license to RTI. Absent potential new collaborations, we expect our contract revenues to be comprised primarily of revenues associated with our Healios collaboration, and royalty payments and potential commercial milestone payments from RTI. Grant revenue varies from period-to-period with new and completed grants, and the timing of grant-funded activities. Absent new grant awards, we expect our annual grant revenue to decline in 2018 from 2017 with the expiration of certain grant-funded programs.

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Research and Development Expenses. Research and development expenses increased to $8.9 million for the three months ended March 31, 2018 from $5.6 million in the comparable period in 2017. The $3.3 million increase is primarily comprised of an increase in preclinical and clinical development costs of $2.7 million, an increase in personnel costs of $0.3 million, and an increase in internal research supplies and other research costs of $0.3 million. The increase in our clinical and preclinical costs during the period is primarily a result of increased process development activities to support large-scale manufacturing, clinical product manufacturing costs, a portion of which are invoiced to Healios, and technology transfer services on Healios behalf in Japan that are reimbursed to us by Healios at cost. Our clinical development, clinical manufacturing, and manufacturing process development costs vary over time based on the timing and stage of clinical trials underway, manufacturing campaigns for trials, and manufacturing process development projects. We expect our annual research and development expenses to increase in 2018 compared to 2017 related to these activities, including the launch of the MASTERS-2 stroke trial. 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 $2.7 million for the three months ended March 31, 2018 from $2.1 million in the comparable period in 2017. The $0.6 million increase was due primarily to an increase of $0.3 million in professional fees, and increases in personnel costs, stock-based compensation costs and other administrative costs compared to the same period last year. We expect our annual 2018 general and administrative expenses to increase as compared to 2017 with the implementation of a new enterprise resource planning system and increased professional fees.

Depreciation. Depreciation expense was consistent at $0.2 million for the three months ended March 31, 2018 and March 31, 2017, respectively. We expect that our depreciation will increase somewhat in the 2018 year from the 2017 year due to new equipment requirements for process development activities.

Gain from Insurance Proceeds. 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 February 2018, we received an additional $0.4 million in insurance proceeds.

Income from Change in Fair Value of Warrants. We had no income recognized during the three months ended March 31, 2018 for the market value change in our warrant liabilities, since as of March 31, 2018, all of our warrants were either exercised or expired, other than the Healios Warrant. For the comparable period of 2017, we had $0.7 million of income reflecting primarily changes in our stock price.

Other Income, net. Other income, net, generally includes interest income and expense, refundable foreign tax credits, foreign currency gains and losses.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances. At March 31, 2018, we had $49.7 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.

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We incurred losses since inception of operations in 1995 and had an accumulated deficit of $359 million at March 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 used all of our sources of capital to develop our technologies, to discover and develop therapeutic product candidates, develop business collaborations and to acquire certain technologies and assets.

As addressed herein, if the expansion of our collaboration with Healios is concluded as contemplated under the LOI, we expect to receive, at a minimum, the $10 million license fee that has been funded by Healios into an escrow account. If the full expansion is consummated, the LOI provides that we would be entitled to receive additional payments of $25 million, as well as additional possible payments such as milestones and royalties. Under the proposed collaboration expansion agreement, this $25 million payment obligation would be paid in instalments that cannot be terminated over time, and though the payments would be non-refundable, they could be used as credits against certain milestone payments due under the license.

For the ischemic stroke indication under the existing 2016 license with Healios, we may receive additional success-based development, regulatory approval and sales milestones of $225 million in aggregate, subject to certain potential milestone credits, and tiered royalties on product sales that start in the low double digits and increase incrementally into the high teens depending on net sales levels. Additionally, we receive payments for product supplied to Healios under a manufacturing supply agreement, which is initially focused on clinical product supply, and in 2017, we agreed to a cost-sharing arrangement with Healios for clinical product for its TREASURE trial in Japan that may impact the amount of proceeds we receive from future milestones.

In connection with the entry into the LOI, Healios purchased 12,000,000 shares of our common stock for $21,100,000, or approximately $1.76 per share, and the Warrant to purchase up to an additional 20,000,000 shares of common stock. The Warrant will become exercisable once Healios makes the initial payment under the planned expansion under the proposed collaboration expansion agreement, except with respect to 4,000,000 shares underlying the Warrant that would become exercisable prior to such time upon release of the $10 million that is funded into escrow, depending on the scope of the expansion. The Warrant has a term that expires in September 2020 (subject to a potential extension), includes both fixed and floating exercise price mechanisms, and is capped such that in no event will Healios own more than 19.9% of our common stock. We may receive additional proceeds from the exercise of the Warrant over its term, although there can be no assurances that Healios will exercise the Warrant in whole or in part.

We have had an equity purchase arrangement in place with Aspire Capital since 2011 that has provided us the ability to sell shares to Aspire Capital from time-to-time, as appropriate, through two-to-three year equity facilities, each with similar terms. Our current arrangement with Aspire Capital that was entered into in February 2018 includes Aspire Capital s commitment to purchase up to an aggregate of $100 million of shares of common stock over a three-year period and 450,000 shares of common stock were issued as a commitment fee. We filed a registration statement for the resale of 24,700,000 shares of common stock in connection with the new equity facility. Furthermore, the prior facility that was entered into in December 2015 with Aspire Capital has approximately 2.0 million shares that remain available to us for issuance. During the quarter ended March 31, 2018, we sold 3,300,000 shares to Aspire Capital at an average price of $1.67 per share. We sold no shares to Aspire Capital in the first quarter of 2017.

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Under the terms of our collaboration agreement with RTI Surgical, Inc., we are eligible to receive $34.5 million in remaining cash payments upon the successful achievement of certain commercial milestones, after the first commercial milestone payment of $1.0 million was achieved in 2017, though there can be no assurances that further such milestones will be achieved. In addition, we receive tiered royalties on worldwide commercial sales of implants using our technologies based on a royalty rate starting in the mid-single digits and increasing into the mid-teens. We began receiving royalties from RTI in 2014 and in the fourth quarter of 2017, a second commercial milestone was achieved, resulting in an increase in the rate of royalties we receive on product sales by RTI, although there can be no assurances that further such milestones resulting in increased royalty rates will be achieved.

We are obligated to pay the University of Minnesota a sublicense fee or a royalty based on worldwide commercial sales of licensed products if covered by a valid licensed patent. The low single-digit royalty rate may be reduced if third-party payments for intellectual property rights are necessary or commercially desirable to permit the manufacture or sale of the product. As of March 31, 2018, we have paid no royalties to the University of Minnesota and have paid sublicense fees from time-to-time in connection with our collaborations.

We will require substantial additional funding in order to continue our research and product development programs, including preclinical evaluation and clinical trials of our product candidates and manufacturing process development. At March 31, 2018, we had available cash and cash equivalents of $49.7 million, and we intend to meet our short-term liquidity needs with available cash. We also have $10 million of license fees related to the planned collaboration expansion with Healios that has been funded in an escrow account to be released to us by June 1, 2018. Over the longer term, we will make use of available cash, but will have to continue to generate additional funding to meet our needs, through business development, achievement of milestones under our collaborations, and grant-funding opportunities. Additionally, we may raise capital from time to time through our equity purchase agreement, subject to its volume and price limitations. We also manage our cash by deferring certain discretionary costs and staging certain development costs to extend our operational runway, as needed. Over time, we may consider the sale of additional equity securities, or possibly borrowing from financing institutions.

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

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

Cash Flow Analysis

Net cash used in operating activities was $5.7 million for the three months ended March 31, 2018 and $5.4 million for the three months ended March 31, 2017, reflecting the increased net loss in the first quarter of 2018 (i.e., cash used to fund preclinical and clinical development activities), compared to the prior year period, as partially offset by proceeds received from Healios for the cost-share arrangement for clinical product supply, and an increase in

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accounts payable due to service providers, such as contract manufacturers, under longer-term contracts. Net cash used in operating activities may fluctuate significantly on a quarter-to-quarter basis, as it has over the past several years, primarily due to the receipt of collaboration fees and payment of specific clinical trial costs, such as clinical manufacturing campaigns, contract research organization costs and manufacturing process development projects, and we expect it to increase in 2018 as compared to 2017 with the launch of our MASTERS-2 clinical trial, among other things.

Net cash used in investing activities was $0.3 million and $0.1 million in the three-month periods ended March 31, 2018 and 2017, respectively. We expect that our capital expenditures for equipment will increase in 2018 compared to 2017.

Financing activities provided cash of $26.3 million for the three months ended March 31, 2018, which primarily included the $21.1 million investment in us by Healios and proceeds from the issuance of common stock to Aspire Capital under our equity purchase agreement in the first quarter of 2018, net of offering costs. Financing activities provided cash of $22.7 million for the three months ended March 31, 2017 related primarily to $20.9 million net proceeds from the February 2017 stock offering and $1.9 million from the exercise of common stock warrants.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Critical Accounting Policies and Management Estimates

The Securities and Exchange Commission, or SEC, defines critical accounting policies as those that are, in management s view, important to the portrayal of our financial condition and results of operations 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 U.S. 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 description of these accounting policies and estimates is included in Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2017. There have been no material changes in our accounting policies and estimates as described in our Annual Report on Form 10-K for the year ended December 31, 2017, except as it relates to the adoption of ASC 606 on January 1, 2018, for which our accounting policy is included in Note 3 to the financial statements.

For additional information regarding our accounting policies, see Note B to the Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2017.

Cautionary Note on Forward-Looking Statements

This Quarterly Report on Form 10-Q 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,

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.

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

our ability to work with Healios under the LOI to successfully negotiate the terms of and execute the documents necessary to expand our existing collaboration;

our ability to raise capital to fund our operations;

the timing and nature of results from our MultiStem clinical trials, including the MASTERS-2 Phase 3 clinical trial and the Healios TREASURE clinical trial in Japan;

the possibility of delays in, adverse results of, and excessive costs of the development process;

our ability to successfully initiate and complete clinical trials of our product candidates;

the possibility of delays, work stoppages or interruptions in manufacturing by third parties or us, such as due to material supply constraints or regulatory issues;

uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the treatment of stroke, AMI and ARDS, and the prevention of GvHD and other disease indications;

changes in external market factors;

changes in our industry s overall performance;

changes in our business strategy;

our ability to protect and defend our intellectual property and related business operations, including the successful prosecution of our patent applications and enforcement of our patent rights, and operate our business in an environment of rapid technology and intellectual property development;

our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies;

our ability to meet milestones and earn royalties under our collaboration agreements, including the success of our collaboration with Healios;

our collaborators ability to continue to fulfill their obligations under the terms of our collaboration agreements;

the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in the United States, Europe and Japan;

our possible inability to execute our strategy due to changes in our industry or the economy generally;

changes in productivity and reliability of suppliers;

the success of our competitors and the emergence of new competitors; and

the risks mentioned elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2017 under Item 1A, Risk Factors.

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

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Item 3. 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 March 31, 2018, we had no investments.

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

Item 4. Controls and Procedures.
Disclosure controls and procedures

Our management, under the supervision of and with the participation of our Chief Executive Officer and our Senior Vice President of Finance, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon this evaluation, our Chief Executive Officer and Senior Vice President of Finance have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

Changes in internal control over financial reporting

During the last fiscal quarter covered by this Quarterly Report on Form 10-Q, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds
During the quarter ended March 31, 2018, we sold an aggregate of 3,300,000 shares of common stock to Aspire Capital under our equity purchase agreement, generating aggregate proceeds of $5.5 million. Each issuance of these unregistered shares qualifies as an exempt transaction pursuant to Section 4(2) of the Securities Act of 1933. Each issuance qualified for exemption under Section 4(2) of the Securities Act of 1933 because none involved a public offering. Each offering was not a public offering due to the number of persons involved, the manner of the issuance and the number of securities issued. In addition, in each case Aspire Capital had the necessary investment intent.

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Item 6. Exhibits.

Exhibit No.	Description
4.1	Common Stock Purchase Warrant issued to HEALIOS K.K. by Athersys, Inc., dated as of March 14, 2018.
10.1	Security Purchase Agreement, by and between Athersys, Inc. and HEALIOS K.K., dated as of March 13, 2018.
10.2	Investor Rights Agreement, by and between Athersys, Inc. and HEALIOS K.K., dated as of March 13, 2018.
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

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SIGNATURES

Pursuant to the requirements 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.

ATHERSYS, INC.

Date: May 10, 2018

/s/ Gil Van Bokkelen
Gil Van Bokkelen
Chairman and Chief Executive Officer
(principal executive officer authorized to sign on behalf of the registrant)

/s/ Laura K. Campbell
Laura K. Campbell
Senior Vice President of Finance
(principal financial and accounting officer authorized to sign on behalf of the registrant)