ATHERSYS, INC / NEW
Form 10-Q
November 06, 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 September 30, 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	**(I.R.S. Employer**
of incorporation or organization)	**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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided 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 November 1, 2018 was 141,745,860.

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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)

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	**$ 47,967**	$ 29,316
Accounts receivable	**573**	586
Accounts receivable from Healios	**582**	153
Unbilled accounts receivable from Healios	**6,670**	
Prepaid expenses and other	**2,183**	1,135
Contractual right to consideration from Healios	**440**	
Other asset related to Healios	**4,220**	
Total current assets	**62,635**	31,190
Equipment, net	**3,002**	2,206
Deposits and other	**892**	197
Total assets	**$ 66,529**	$ 33,593
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	**$ 10,084**	$ 4,469
Accrued compensation and related benefits	**1,366**	1,065
Accrued clinical trial related costs	**1,774**	1,453
Accrued expenses	**273**	425
Accrued license fee expense	**250**	1,900
Deferred revenue		771
Total current liabilities	**13,747**	10,083
Advances from Healios	**2,445**	134
Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at September 30, 2018 and December 31, 2017		
Common stock, $0.001 par value; 300,000,000 shares authorized, and 140,237,278 and 122,077,453 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	**140**	122
Additional paid-in capital	**411,918**	373,884

Accumulated deficit		**(361,721)**		(350,630)
Total stockholders equity		**50,337**		23,376
Total liabilities and stockholders equity	**$**	**66,529**	$	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 per share data)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	**2018**	2017
Revenues				
Contract revenue from Healios	**$ 1,906**	$	**$ 21,009**	$ 267
Royalty and other contract revenue	**312**	179	**1,304**	1,621
Grant revenue	**103**	220	**465**	650
Total revenues	**2,321**	399	**22,778**	2,538
Costs and expenses				
Research and development	**9,545**	5,441	**28,490**	15,707
General and administrative	**2,556**	2,113	**7,596**	6,391
Depreciation	**196**	177	**573**	508
Total costs and expenses	**12,297**	7,731	**36,659**	22,606
Gain from insurance proceeds			**383**	
Loss from operations	**(9,976)**	(7,332)	**(13,498)**	(20,068)
Income from change in fair value of warrants				728
Other income, net	**236**	89	**536**	199
Net loss and comprehensive loss	**$ (9,740)**	$ (7,243)	**$ (12,962)**	$ (19,141)
Net loss per share, basic and diluted	**$ (0.07)**	$ (0.06)	**$ (0.10)**	$ (0.17)
Weighted average shares outstanding, basic and diluted	**138,930**	114,515	**134,728**	109,506

See accompanying notes to unaudited condensed consolidated financial statements.

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Athersys, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine months ended September 30,	
	2018	2017
Operating activities		
Net loss	**$ (12,962)**	$ (19,141)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**573**	508
Stock-based patent license and settlement expense	**315**	
Stock-based compensation	**2,733**	2,232
Discount on revenue from issuance of warrant	**1,080**	
Deferred revenue from prior period	**(250)**	
Change in fair value of warrant liabilities		(728)
Changes in operating assets and liabilities:		
Accounts receivable	**13**	(109)
Accounts receivable from Healios - billed and unbilled	**(7,069)**	
Prepaid expenses, deposits and other	**(1,743)**	(125)
Contractual right to consideration from Healios	**996**	
Accounts payable and accrued expenses	**5,335**	(1,015)
Deferred revenue		503
Advances from Healios	**2,195**	
Net cash used in operating activities	**(8,784)**	(17,875)
Investing activities		
Purchases of equipment	**(1,369)**	(168)
Net cash used in investing activities	**(1,369)**	(168)
Financing activities		
Proceeds from issuance of common stock, net	**29,105**	29,863
Shares retained for withholding tax payments on stock-based awards	**(301)**	(200)
Proceeds from exercise of warrants		1,861
Net cash provided by financing activities	**28,804**	31,524
Increase in cash and cash equivalents	**18,651**	13,481
Cash and cash equivalents at beginning of the period	**29,316**	14,753
Cash and cash equivalents at end of the period	**$ 47,967**	$ 28,234

See accompanying notes to unaudited condensed consolidated financial statements.

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Athersys, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Three- and Nine-Month Periods Ended September 30, 2018 and 2017

1. Background and Basis of Presentation

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

We have incurred losses since our inception in 1995 and had an accumulated deficit of $361.7 million at September 30, 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. At September 30, 2018, we had available cash and cash equivalents of $48.0 million. 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.

Use of Estimates: 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.

Reclassifications: Certain reclassifications have been made to the 2017 condensed consolidated financial statements to separately disclose revenue and certain balance sheet accounts related to HEALIOS K.K. (Healios) to conform to the presentation in the current year.

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2. Recently Issued Accounting Standards

In August 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 2018-05 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 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 2018-05, 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 as well as whether we will 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 on their balance sheets but recognize expenses on their income statements in a manner similar to current accounting practice. Under the guidance, lessees initially recognize a lease liability for the obligation to make lease payments and a right-of-use (ROU) asset for the right to use the underlying asset for the lease term. The lease liability is measured at the present value of the lease payments over the lease term. The ROU asset is measured at the lease liability amount, adjusted for lease prepayments, lease incentives received and the lessee s initial direct costs. The guidance is effective for the annual and interim periods beginning after December 15, 2018, with early adoption permitted. We 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 are being evaluated under this new guidance. We are also reviewing our current contracts to determine if there are any effective embedded facility leases.

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. We adopted this standard effective January 1, 2018, and its adoption 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.

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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 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 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.

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 6.

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 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 will be 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.

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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 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 are not yet billed. At September 30, 2018, the unbilled accounts receivable from Healios was $6.7 million, which includes $5.0 million of license fees that are being paid to us by Healios in $2.5 million installments over the next two quarters related to the expansion described in Note 6. The two unpaid installments are included in unbilled accounts receivable on the condensed consolidated balance sheets.

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 is classified as a current obligation, as opposed to non-current. In the second quarter of 2018, we recognized $250,000 of revenue that was deferred as of January 1, 2018 since the associated agreement concluded in the second quarter of 2018.

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 their ischemic stroke trial. The proceeds from Healios that relate specifically to the cost-sharing arrangement may result in a decrease in the amount of proceeds we receive from Healios upon the achievement of two future milestones, and an increase to a late-stage commercial milestone, if the cost-share amounts are not 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 stroke study in Japan 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- and nine-month periods ended September 30, 2018, no revenue was recognized related to these advances.

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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 subsequent modifications to the 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 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):

	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)
Equity			
Accumulated deficit	$ 350,630	$ (1,871)	$ 348,759

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In accordance with the new revenue recognition requirements, the disclosure of the impact of adoption on our condensed consolidated balance sheet as of September 30, 2018 and statement of operations for the three- and nine-month periods ended September 30, 2018 was as follows (in thousands, except per share data):

	As of September 30, 2018		
	As Reported	Balances without Adoption of Topic 606	Effect of Change
Assets			
Unbilled accounts receivable from Healios	$ 6,670	$ 1,670	$ 5,000
Contractual right to consideration from Healios	$ 440	$	$ 440
Liabilities			
Deferred revenue	$	$ (2,518)	$ 2,518
Equity			
Accumulated deficit	$ 361,721	$ 369,679	$ (7,958)

	Three Months ended September 30, 2018			Nine months ended September 30, 2018		
	As Reported	Balances without Adoption of Topic 606	Effect of Change	As Reported	Balances without Adoption of Topic 606	Effect of Change
Revenues						
Contract revenues from Healios	$ 1,906	$ 3,790	$ (1,884)	$ 21,009	$ 14,922	$ 6,087
Net loss	$ (9,740)	$ (7,856)	$ 1,884	$ (12,962)	$ (19,049)	$ (6,087)
Net loss per common share						
Basic and diluted	$ (0.07)	$ (0.06)	$ 0.01	$ (0.10)	$ (0.14)	$ (0.04)

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. See Note 6 for the discussion of the elements to Healios revenue and the accounting treatment of a related warrant. The following table presents our contract revenues disaggregated by timing of revenue recognition and excludes royalty revenue (in thousands):

	Three months ended September 30, 2018		Nine months ended September 30, 2018	
	Point in Time	Over Time	Point in Time	Over Time
Contract revenue from Healios				
License fee revenue			$ 17,682	
Product supply revenue	$ 209		651	
Service revenue		$ 1,697		$ 2,676
Other contract revenue	1		251	
Total disaggregated revenues	**$ 210**	**$ 1,697**	**$ 18,584**	**$ 2,676**

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. In connection with the purchase of shares of our common stock by Healios in March 2018, a warrant was issued to Healios (the Healios Warrant) to purchase up to an additional 20,000,000 shares of common stock (the Warrant Shares). Refer to Note 8 for additional details. Since Healios is currently permitted to exercise only a portion of the Warrant Shares and the exercise price for the portion of the Warrant Shares that is currently exercisable is contractually above market price, the entire Healios Warrant is anti-dilutive as of September 30, 2018. The following instruments (in thousands) were excluded from the calculation of diluted net loss per share because their effects would be antidilutive:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	**2018**	2017
Stock-based awards	**12,600**	10,880	**12,600**	10,880
Healios Warrant see Note 8	**20,000**		**20,000**	

Total	**32,600**	10,880	**32,600**	10,880

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.

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6. Collaborative Arrangements and Revenue Recognition

Healios

Collaboration

In 2016, we entered into a license agreement (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 its organ bud program, initially for transplantation to treat liver disease or dysfunction. Under the terms of the First License Agreement, we received a nonrefundable, up-front cash payment of $15 million in 2016. Under the First License 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), for $10 million. For the ischemic stroke indication, we may receive payments for 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.

In June 2018, Healios exercised its option to expand the collaboration to include ARDS and 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 broadened the collaboration beyond that contemplated in the First License Agreement. Under the CEA, Healios (i) expanded its license 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 to the First License Agreement; (ii) obtained a worldwide exclusive license for use of MultiStem product to treat certain ophthalmological indications; (iii) obtained an exclusive license in Japan for use of the MultiStem product to treat diseases of the liver, kidney, pancreas and intestinal tissue through local administration of MultiStem products in combination with iPSC-derived cells; (iv) obtained an exclusive, time-limited right of first negotiation to enter into an option for a license to develop and commercialize MultiStem products for ischemic stroke, ARDS and trauma in China; and (v) received certain other rights. For all indications, Healios is responsible for the costs of clinical development in its licensed territories. We provide manufacturing services to Healios, currently comprising the supply of product for its clinical trials and preparations for commercial manufacturing, and we receive payments for product supplied to Healios. We also receive financial support from Healios for technology transfer services we provide to a contract manufacturer in Japan to produce product for Healios. The costs of the services are reimbursed by Healios at our cost.

For the rights granted to Healios under the CEA, Healios paid to Athersys a nonrefundable, up-front cash payment of $10 million to exercise its option to license ARDS and expand its license for organ bud, as contemplated by the First License Agreement, and in June 2018, made the first of four quarterly installment payments of $2.5 million in connection with the agreement granting it new license rights. As of September 30, 2018, two quarterly payments remain due according to the terms of the CEA. Healios may elect to credit up to $10 million against milestone payments that may become due under the First License Agreement, with limitations on amounts that may be credited to earlier milestone payments versus later milestone payments.

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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 supply manufacturing services to Healios for its stroke study and technology transfer services that we provide to a contract manufacturer in Japan. In the third quarter of 2018, the terms were agreed upon for clinical supply 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. Following this modification, the remaining transaction price for the performance obligations that were not yet delivered amounted to $4.8 million at September 30, 2018, which is expected to be recognized within one year as the goods and services are delivered.

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, a specific portion (4,000,000 Warrant Shares) became exercisable, while the remainder (16,000,000 Warrant Shares) become exercisable upon Healios agreement to execute an option for a license for an expansion into China (refer to Note 8). As a result, $1.1 million was recorded in June 2018 as a reduction of license fee revenue.

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 for Healios that are satisfied over time, we recognize revenue in proportion to the contractual services provided. At September 30, 2018, the contract asset is properly classified as a current asset since the conditional rights to consideration are expected to be satisfied, in all material respects, within one year.

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 and the issuance of the Healios Warrant in connection with the expansion of the collaboration.

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Other

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 are eligible to receive 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.

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 nonrefundable option fee, which was initially recorded as deferred revenue, was recognized in the second quarter of 2018 as the agreement had expired. The evaluation of our technology for animal health applications continues.

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. In the three-month period ended September 30, 2018, we granted 90,192 stock options to our employees. As of September 30, 2018, a total of 4,915,082 shares (including 248,703 shares related to an expired incentive plan) of common stock have been issued under our equity incentive plans.

As of September 30, 2018, a total of 3,699,221 shares were available for issuance under our equity incentive plan, and stock-based awards to purchase 12,600,393 shares (including 930,993 shares related to an expired incentive plan) of common stock were outstanding. For the three-month periods ended September 30, 2018 and 2017, stock-based compensation expense was approximately $1.1 million and $0.8 million, respectively. At September 30, 2018, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately $9.3 million, which is expected to be recognized by the end of 2022 using the straight-line method.

8. Stockholders Equity

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.

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The value of the Healios Warrant was considered as an element of compensation in the transaction price of the Healios expansion, as discussed in Note 6. The Healios Warrant originally did not become effective until the CEA became effective in June 2018 and the first payment was made under the expansion. Upon such effectiveness, the Healios Warrant became exercisable with respect to 4,000,000 Warrant Shares, and the remaining 16,000,000 Warrant Shares will become exercisable if Healios agrees to execute an option for a license in China. This period was originally scheduled to expire in September 2018; however, it was extended in the third quarter of 2018 to December 2018. Other important Healios Warrant terms include expiration 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 was appropriately accounted for as equity 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 will be included as an element of compensation in the transaction price if Healios executes an option for a license for an expansion into China in December 2018.

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 shares underlying the Healios Warrant that was related to the June 2018 expansion of $1.1 million was recorded as a reduction to the revenue recognized for the delivered licenses in June 2018. The modification in the third quarter of 2018 to increase the expiration date from September 2018 to December 2018 related to a potential China expansion provided no incremental fair value to be recorded in the period.

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, our prior facility that was entered into in December 2015 with Aspire Capital had approximately 500,000 shares available to us for issuance as of September 30, 2018 that were subsequently issued in October 2018, fully utilizing the prior facility.

We sold 1,500,000 shares to Aspire Capital at an average price of $1.90 in the third quarter of 2018, generating proceeds of $2.9 million. We sold 4,800,000 shares to Aspire Capital at an average price of $1.74 per share during the nine-months ended September 30, 2018, generating proceeds of $8.4 million. We sold 3,700,000 shares to Aspire Capital generating aggregate proceeds of $6.6 million in the third quarter of 2017 and 5,350,000 shares generating aggregate proceeds of $9.0 million during the nine months ended September 30, 2017.

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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 $0.5 million 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 agreed to pay an additional $0.25 million per quarter for four quarters, of which one final installment is due in the fourth quarter of 2018. Additionally, in May 2018, upon the issuance of a patent from the party s patent applications at the core of the dispute, we issued 500,000 additional shares of our common stock. This contingent obligation to issue 500,000 shares of common stock was originally recorded in accrued license fee expense on the condensed consolidated balance sheets at December 31, 2017 at a fair value $0.9 million. The actual issuance of the shares in May 2018 was recorded at a fair value of $1.2 million, resulting in $0.3 million of additional paid-in-capital and research and development expense. Upon payment of the final installment of $0.25 million in the fourth quarter of 2018, our payment obligations will be concluded.

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.

At September 30, 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 that represented a Level 3 equity instrument under the hierarchy. Refer to Note 8 regarding its valuation and subsequent modifications.

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 (IRC) of 1986, as amended. We generated U.S. federal net operating loss carryforwards, research and development tax credits, and state and local net operating loss carryforwards since 2012 which may be limited under Section 382 of the IRC. We will update our analysis under Section 382 of the IRC prior to using these attributes.

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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 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 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 provisional Transition Tax obligation.

The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin 118, Income Tax Accounting Implications of the TCJA (SAB 118), which provided guidance on accounting for the tax effects of TCJA. Pursuant to SAB 118, we had provisional calculations related to the enacted legislation which were finalized after the underlying timing differences and foreign earnings and profits were finalized with our 2017 federal tax return filing. No further adjustments were recorded as of September 30, 2018 related to the new legislation. We are still analyzing certain aspects of the Tax Act which could potentially affect the measurement of these balances or potentially give rise to new or additional deferred tax amounts.

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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 clinical development in several areas, the most advanced of which is an ongoing Phase 3 clinical trial for treatment of ischemic stroke. 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 establish therapeutic product development programs, and our programs in the clinical development stage include the following:

Ischemic Stroke: We recently 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 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, or RMAT, 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.

In addition, HEALIOS K.K., or 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.

Acute Respiratory Distress Syndrome, or ARDS: We recently completed enrollment in our Phase 1/2 clinical study for the treatment of ARDS in the United Kingdom and in the United States designed to evaluate the safety and feasibility of treating certain ARDS subjects. We will announce the study results upon completion of data gathering and analysis, which is expected in the first quarter of 2019.

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. We 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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Hematopoietic Stem Cell Transplant / Graft-vs-Host Disease, or GvHD: Currently, this program is staged for future registration-directed development, which depends on the success and impact of the development of alternative therapies for treating the underlying conditions leading to transplant and 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 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.

Trauma: We recently announced with the University of Texas Health Science Center at Houston 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 are in the planning and preparation stage for this study and will provide further updates as preparations for the trial progress.

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 while the agreement has expired, the evaluation is ongoing.

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.

We have a collaboration with Healios covering MultiStem cell therapy for ischemic stroke in Japan and the use of our technology for Healios organ bud program initially 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. Healios also has a right of first negotiation that currently expires in December 2018 for an option to license certain indications in China. We 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.

We also have a collaboration with RTI Surgical, Inc., or RTI, for the development of products for certain orthopedic applications using our stem cell technologies in the bone graft substitutes market, and we receive royalty revenue from product sales and have potential for other payments from time to time associated with achievement of certain commercial milestones. No milestones were achieved in the nine months ended September 30, 2018. Additionally, we expect that RTI may reduce or even cease commercial sales of the current product for regulatory and strategic reasons.

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Financial

As addressed herein, upon the expansion of our collaboration with Healios that was completed in June 2018, we received $10 million of license fees for the ARDS and organ bud expansion. Additionally, we are receiving four quarterly installments of $2.5 million (the first two were received in June 2018 and August 2018) related to the license of certain ophthalmology and combination product rights. We are also entitled to receive potential milestones payments and royalties from Healios, as well as potential additional fees upon further expansion that may include an option to license our technologies for development in China, for which Healios has a right of first negotiation that currently expires in December 2018. Furthermore, we 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 be due in the future.

In connection with the expansion, in March 2018, Healios purchased 12,000,000 shares of our common stock for $21.1 million, or approximately $1.76 per share, and received a warrant, or the Healios Warrant, to purchase up to an additional 20,000,000 shares of common stock. The Healios Warrant is currently exercisable with respect to 4,000,000 shares underlying the Healios Warrant, with the remainder becoming exercisable in the event that Healios and Athersys enter into an option agreement in December 2018 for the license of certain development and commercialization rights in China. The Healios Warrant may be terminated by us under certain conditions. As of September 30, 2018, no shares have been issued pursuant to an exercise of the Healios Warrant. See also Note 8 to the condensed consolidated financial statements.

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 had shares that remained available to us for issuance, which were issued in the fourth quarter of 2018, fully utilizing the prior facility. During the quarter ended September 30, 2018, we sold 1,500,000 shares to Aspire Capital at an average price of $1.90; and year-to-date, we have sold 4,800,000 shares at an average price of $1.74.

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 September 30, 2018.

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.

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Three Months Ended September 30, 2018 and 2017

Revenues. Revenues increased by $1.9 million to $2.3 million for the three months ended September 30, 2018 compared to $0.4 million for the three months ended September 30, 2017. Our revenues are generally derived from license fees, manufacturing-related activities for Healios, royalty and related contract revenue from our collaborations and grant revenue. Grant revenue decreased approximately $0.1 million in the third quarter of 2018 compared to the prior year third quarter.

Research and Development Expenses. Research and development expenses increased to $9.5 million for the three months ended September 30, 2018 from $5.4 million for the comparable period in 2017. The increase is primarily associated with increased clinical development costs of $3.0 million, increased personnel costs of $0.6 million, increased license fees of $0.2 million and increased internal research supplies of $0.2 million. The increase in our clinical costs during the period is primarily a result of increased clinical product manufacturing costs, a portion of which are invoiced to Healios, technology transfer services on Healios behalf in Japan that are invoiced to Healios, process development activities to support large-scale manufacturing, and costs related to our MASTERS-2 clinical trial that began enrolling patients in the third quarter of 2018. 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, and we expect our annual 2018 clinical development costs to increase as compared to 2017. 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 generally 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 $2.6 million for the three months ended September 30, 2018 compared to $2.1 million in the comparable period in 2017. The $0.5 million increase was primarily due to increased legal and professional fees, consulting services and personnel costs. 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, increased professional fees and additional personnel costs.

Depreciation. Depreciation expense was consistent at $0.2 million for the three months ended September 30, 2018 and September 30, 2017, respectively. We expect that our annual depreciation will increase in 2018 compared to 2017 due to new equipment requirements, primarily for process development activities.

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

Nine Months Ended September 30, 2018 and 2017

Revenues. Revenues increased to $22.8 million for the nine months ended September 30, 2018 from $2.5 million in the comparable period in 2017. Our contract revenues from our collaboration with Healios increased $20.8 million period over period, reflecting the expansion of our collaboration in June 2018 to include several additional licensed indications, among other things.

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Research and Development Expenses. Research and development expenses increased to $28.5 million for the nine months ended September 30, 2018 from $15.7 million in the comparable period in 2017. The increase of $12.8 million related primarily to an increase in clinical costs of $9.8 million, an increase in personnel costs of $1.2 million, an increase in license fees of $0.9 million and an increase in research supplies of $0.6 million. The increase in our clinical costs during the period is primarily a result of increased clinical product manufacturing costs, a portion of which are invoiced to Healios, technology transfer services on Healios behalf in Japan that are invoiced to Healios, and process development activities to support large-scale manufacturing. Other than external expenses for our clinical and preclinical programs, we generally do not track our research expenses by project; rather, we track such expenses by the type of cost incurred.

General and Administrative Expenses. General and administrative expenses increased to $7.6 million for the nine months ended September 30, 2018 from $6.4 million in the comparable period in 2017. The $1.2 million increase was due primarily to an increase in legal and professional fees, personnel costs and consulting services compared to the same period in 2017, which includes costs related to the implementation of a new enterprise resource planning system in 2018.

Depreciation. Depreciation expense of $0.6 million for the nine months ended September 30, 2018 was slightly higher compared to $0.5 million for the comparable period in 2017 due to new equipment requirements, primarily for process development activities.

Income from Change in Fair Value of Warrants, net. We did not recognize a change in fair value of warrants during the nine months ended September 30, 2018. As of September 30, 2018, other than the Healios Warrant, all of our prior warrants were either exercised or expired. For the comparable period of 2017, we had $0.7 million of income primarily reflecting changes in our stock price for warrants that have now expired.

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 2018, we received an additional $0.4 million in insurance proceeds.

Other Income, net. Other income, net, was $0.5 million for the nine-month period ended September 30, 2018 and $0.2 million for the comparable 2017 period, and is comprised of interest income and expense, and net foreign currency gains and losses.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances. At September 30, 2018, we had $48.0 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 $361.7 million at September 30, 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, to discover and develop therapeutic product candidates, develop business collaborations and to acquire certain technologies and assets.

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As addressed herein, we received $10 million of license fees and, in addition, have been receiving quarterly installments of $2.5 million (we received the first two of four installments per the terms of the agreement) from the expansion of our collaboration with Healios that was completed in June 2018. We are also entitled to receive potential milestones payments, subject to certain credits, and royalties from Healios, as well as potential additional fees upon further expansion that may include an option to license our technologies for development in China, for which Healios has a right of first negotiation that expires in December 2018. Furthermore, we 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 be due in the future.

In connection with the June 2018 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, with the remainder becoming exercisable in the event that Healios executes an option to expand into the China territory for certain indications in December 2018. The Healios Warrant has a 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 September 30, 2018, no shares have been issued pursuant to an exercise of the Healios Warrant.

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. The prior facility that was entered into in December 2015 with Aspire Capital was fully utilized in the fourth quarter of 2018. During the quarter ended September 30, 2018, we sold 1,500,000 shares to Aspire Capital at an average price of $1.90 per share. For the nine months ended September 30, 2018 we sold 4,800,000 shares to Aspire Capital at an average price of $1.74 per share. During the three-month period ended September 30, 2017, we sold 3,700,000 shares to Aspire Capital at an average price per share of $1.78 per share. For the nine months ended September 30, 2017 we sold 5,350,000 shares to Aspire Capital at an average price of $1.68 per share.

Under the terms of our collaboration agreement with RTI, we are eligible to receive cash payments upon the successful achievement of certain commercial milestones. In addition, we receive tiered royalties on worldwide commercial sales of implants using our technologies. We began receiving royalties from RTI in 2014 and received a commercial milestone payment of $1.0 million in 2017. There can be no assurances about the nature and levels of RTI product sales in the future and, therefore, the related royalty and milestone payments by RTI to us.

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 September 30, 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, including our Healios collaboration. We have other obligations related to academic licensors that are less significant than our obligation to University of Minnesota, and we may continue to enter into such licenses from time to time.

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We will require 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 September 30, 2018, we had available cash and cash equivalents of $48.0 million, and we intend to meet our short-term liquidity needs with available cash. Over the longer term, we will make use of available cash, but will have to continue to generate additional funding to meet our needs, through business development, achievement of milestones under our collaborations, and grant-funding opportunities. Additionally, we may raise capital through our equity purchase agreement, subject to its volume and price limitations, and Healios may exercise the Healios Warrant from time to time. 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 borrow 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.

Cash Flow Analysis

Net cash used in operating activities was $8.8 million for the nine months ended September 30, 2018 compared to cash used of $17.9 million for the nine months ended September 30, 2017, reflecting, among other things, the receipt of $15.0 million of license fees from our 2018 expansion with Healios, partially offset by an increase in the use of cash to fund clinical and preclinical development activities. The $15.0 million of license fees represents $10.0 million that was received in June 2018 and two of four installments of $2.5 million, with the remaining two installments scheduled to be received over the next two quarters. 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 fees from our collaborators 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 by investing activities was $1.4 million and $0.2 million for the nine-months ended September 30, 2018 and 2017, respectively. The fluctuations over the periods were due to the purchase of equipment primarily for our manufacturing process development activities. We expect that our capital equipment expenditures will increase in 2018 compared to 2017.

Financing activities provided cash of $28.8 million for the nine-months ended September 30, 2018, which constituted primarily 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, net of offering costs. Financing activities provided cash of $31.5 million

for the nine months ended September 30, 2017, including $20.9 million of net proceeds from a February 2017 common stock offering, equity sales to Aspire Capital and the exercise of common stock warrants, net of shares retained for withholding tax payments on stock-based awards.

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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 quarterly report.

In addition, a number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements. Some of the more significant known risks that we face are the risks and uncertainties inherent in the process of discovering, developing, and commercializing products that are safe and effective for use as 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, contaminations, or regulatory issues, which could negatively impact our trials and the trials of our collaborators;

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uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the treatment of 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 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 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.

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 September 30, 2018, we had no investments.

We have entered into loan arrangements with financial institutions when needed and when available to us. At September 30, 2018, we had no borrowings outstanding.

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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 September 30, 2018, we sold an aggregate of 1,500,000 shares of common stock to Aspire Capital under our equity purchase agreement, generating aggregate proceeds of $2.9 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
10.1	Amendment No. 1 to Collaboration Expansion Agreement, by and between Athersys, Inc. and HEALIOS K.K., dated as of August 31, 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: November 6, 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)