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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, 2023

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

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

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	ATHX	The NASDAQ Stock Market LLC

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.

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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 May 11, 2023 was 20,870,888.

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, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	**$ 3,121**	$ 9,038
Accounts receivable from Healios	**716**	716
Prepaid clinical trial costs	**2,747**	2,747
Prepaid expenses and other	**1,252**	1,034
Total current assets	**7,836**	13,535
Operating right-of-use assets, net	**7,591**	7,846
Property and equipment, net	**4,079**	4,214
Deposits and other	**2,126**	2,136
Total assets	**$ 21,632**	$ 27,731
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 28,959**	$ 27,765
Operating lease liabilities, current	**675**	746
Accrued compensation and related benefits	**654**	1,090
Accrued clinical trial related costs	**7,258**	7,231
Accrued expenses and other	**974**	1,078
Warrant liability	**1,163**	534
Total current liabilities	**39,683**	38,444
Operating lease liabilities, non-current	**7,762**	7,939
Advance from Healios	**5,199**	5,199
Stockholders' equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at March 31, 2023 and December 31, 2022	**—**	—
Common stock, $0.001 par value; 600,000,000 shares authorized with 18,448,489 and 17,986,147 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	**18**	18
Additional paid-in capital	**632,660**	632,009
Accumulated deficit	**(663,689)**	(655,878)
Total stockholders' equity (deficit)	**(31,011)**	(23,851)
Total liabilities and stockholders' equity	**$ 21,633**	$ 27,731

See accompanying notes to unaudited condensed consolidated financial statements.

Athersys, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)
(Unaudited)

	Three months ended March 31,	
	2023	2022
Revenues		
Contract revenue from Healios	**$ —**	$ 2,912
Total revenues	**—**	2,912
Costs and expenses		
Research and development	**4,467**	20,944
General and administrative	**2,815**	4,099
Depreciation	**52**	247
Total costs and expenses	**7,334**	25,290
Loss from operations	**(7,334)**	(22,378)
Other income, net	**(477)**	162
Net loss and comprehensive loss	**$ (7,811)**	(22,216)
Net loss per share, basic and diluted	**$ (0.43)**	$ (2.27)
Weighted average shares outstanding, basic and diluted	**18,292**	9,768

S*ee accompanying notes to unaudited condensed consolidated financial statements.*

Athersys, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Stated Value	Number of Shares[1]	Par Value			
Balance at December 31, 2022	—	$ —	**17,986,147**	**$ 18**	**$ 632,009**	**$ (655,878)**	**$ (23,851)**
Stock-based compensation	—	—	—	—	**707**	—	**707**
Stock Issue- warrant exercise	—	—	**344,170**	—	—	—	—
Issuance of common stock	—	—	—	—	—	—	—
Issuance of common stock under equity compensation plan	—	—	**118,172**	—	**(56)**	—	**(56)**
Net and comprehensive loss	—	—	—	—	—	**(7,811)**	**(7,811)**
Balance at March 31, 2023	—	—	**18,448,489**	**18**	**632,660**	**(663,689)**	**(31,011)**

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Stated Value	Number of Shares 1	Par Value			
Balance at December 31, 2021	—	$ —	9,713,767	$ 10	$ 599,703	$ (583,344)	$ 16,369
Stock-based compensation	—	—	—	—	1,410	—	1,410
Stock Issue- warrant exercise	—	—	—	—	—	—	—
Issuance of common stock	—	—	129,333	—	4,803	—	4,803
Issuance of common stock under equity compensation plan	—	—	148,611	—	(58)	—	(58)
Net and comprehensive loss	—	—	—	—	—	(22,216)	(22,216)
Balance at March 31, 2022	—	—	9,991,711	10	605,857	(605,560)	307

See accompanying notes to unaudited condensed consolidated financial statements.

[1] Reflects the 1-for-25 reverse stock split that became effective August 26, 2022. Refer to Note 1, "Background and Basis of Presentation."

Athersys, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Three months ended March 31,	
	2023	2022
Operating activities		
Net loss	**(7,811)**	$ (22,216)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**52**	247
Stock-based compensation	**707**	1,410
Change in fair value of warrant liabilities	**629**	—
Changes in operating assets and liabilities:		
Accounts receivable from Healios - billed and unbilled	**—**	(229)
Prepaid expenses, deposits and other	**22**	(217)
Accounts payable, accrued expenses and other	**435**	1,975
Deferred revenue - Healios	**—**	(1,138)
Net cash used in operating activities	**(5,966)**	(20,168)
Investing activities		
Proceeds from the sale of equipment	**105**	—
Purchases of equipment	**—**	(186)
Net cash provided (used) in investing activities	**105**	(186)
Financing activities		
Proceeds from issuance of common stock, net of issuance cost	**—**	4,802
Shares retained for withholding tax payments on stock-based awards	**(56)**	(58)
Net cash (used) provided by financing activities	**(56)**	4,744
Decrease in cash and cash equivalents	**(5,917)**	(15,610)
Cash and cash equivalents at beginning of the period	**9,038**	37,407
Cash and cash equivalents at end of the period	**$ 3,121**	$ 21,797

See accompanying notes to unaudited condensed consolidated financial statements.

Athersys, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
Three Month Periods Ended March 31, 2023 and 2022

1. Background and Basis of Presentation

Organization

Athersys, Inc., including its consolidated subsidiaries (collectively, "we," "us," "our," "Athersys," and the "Company"), is a biotechnology company focused in the field of regenerative medicine and operates in one business segment. Our operations consist of research, clinical development activities, manufacturing and manufacturing process development activities, and our most advanced program is in a pivotal Phase 3 clinical trial for the treatment of ischemic stroke.

Basis of Presentation

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, 2022. The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and 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 and disclosures 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 in this Quarterly Report on Form 10-Q.

Reverse stock split

On August 26, 2022, the Company amended its Certificate of Incorporation to implement a 1-for-25 reverse stock split of its common stock. The reverse stock split did not cause an adjustment to the par value or the authorized shares of the common stock. As a result of the reverse stock split, the Company adjusted the share amounts under its employee equity incentive plans, inducement awards and common stock warrant agreements with third parties. All disclosures of common shares and per common share data in the accompanying interim financial statements and related notes reflect the reverse stock split for all periods presented.

2. Going Concern

We have prepared our unaudited condensed consolidated financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. However, we have incurred net losses since our inception in 1995 and have negative operating cash flows. These factors, among others, raise substantial doubt about our ability to continue as a going concern within one year after the date that these financial statements are issued.

The accompanying unaudited condensed consolidated financial statements do not include any adjustments to reflect the possible future effect on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of the uncertainty concerning our ability to continue as a going concern.

At March 31, 2023, we had cash and cash equivalents of $3.1 million. We will need substantial additional funding to develop our MultiStem product candidate and to continue our operations. Significant additional capital will be required to continue our research and development programs, including progressing our clinical product candidates to potential commercialization and preparing for commercial-scale manufacturing and sales. If we are unable to obtain adequate financing, we likely would have to file for protection under the bankruptcy laws to continue to pursue potential transactions and conduct a wind down of our Company. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders. For the foreseeable future, our ability to continue our operations is dependent upon the ability to obtain additional funding through public or private equity offerings, debt financings, collaborations and/or licensing arrangements. However, there can be no assurance that we will be able to obtain such funding on terms acceptable to us, on a timely basis or at all, particularly in light of our current stock price and liquidity. If we are unable to obtain funding, we may be required to further delay, reduce or eliminate our MultiStem product candidate approval and commercialization efforts, which would adversely affect our business prospects, and we likely will be unable to continue operations. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effect on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of the uncertainty concerning our ability to continue as a going concern.

3. Accounting Standards Adopted

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments (Topic 326)*. This ASU replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Subsequent to issuing ASU 2016-13, the FASB issued ASU 2019-10, *Financial Instruments - Credit Losses (Topic 326): Effective Dates*, delaying the effective date for smaller reporting companies until January 2023. The impact of adoption of this standard did not have a material impact on the consolidated financial statements and disclosures.

4. Net Loss per Share

Basic and diluted net loss per share have been computed using the weighted-average number of shares of our common stock outstanding during the period.

As of March 31, 2023, we have outstanding options, restricted stock units and warrants that were not used in the calculation of diluted net loss per share because to do so would be antidilutive. As of March 31, 2023, we had warrants outstanding to purchase an aggregate of 400,000 shares of our common stock that were issued to HEALIOS K.K. ("Healios") in August 2021 and are not yet exercisable according to their terms. Additionally, as of March 31, 2023, we had outstanding warrants to purchase 1,920,000, 2,000,000, and 9,109,090 shares of our common stock that were issued in August 2022, September 2022, and November 2022, respectively. Refer to Note 8 for additional information.

The following instruments were excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

	Three months ended March 31,	
	2023	2022
Stock options	**1,196,530**	1,307,832
Restricted stock units	**859,282**	66,258
Warrants - refer to Note 8	**13,429,090**	400,000
Total	**15,484,902**	1,774,090

5. Property and Equipment, net

	For the periods ended	
Property and equipment consists of (in thousands):	**March 31, 2023**	December 31, 2022
Laboratory equipment	**7,244**	$ 7,576
Office equipment and leasehold improvements	**3,934**	3,934
Equipment and leasehold improvements not yet in service	**2,313**	2,313
	13,491	13,823
Accumulated depreciation and amortization	**(9,412)**	(9,609)
	$ 4,079	$ 4,214

(9,412)

Long-lived assets are evaluated for impairment when events or changes in circumstances indicate that the carrying amount of the asset or related group of assets may not be recoverable. In June 2022, we announced a restructuring plan (the "Plan") of our organization with the intention of significantly reducing expenses, conserving cash, improving the focus of the Company's activities and becoming more attractive to potential financial and strategic partners. The Plan included a significant reduction in our workforce and changes to our management team. The Plan also includes the reduction of our internal research function, the decommissioning of certain equipment and pausing our manufacturing and process development efforts toward commercializing our MultiStem product candidate. As a result of these actions, during 2022, we recorded impairment charges of approximately $7.2 million to adjust the carrying amount of certain equipment assets to the estimated market value of similar assets, we have not recorded any additional impairment during the period ending March 31, 2023. The impairment charges were included in research and development costs and expenses on the condensed consolidated statements of operations and comprehensive loss starting in June 2022.

As part of the Plan, we have disposed of gross assets of approximately $0.3 million with accumulated depreciation of $0.2 million, for a gain of approximately $0.1 million the period ended March 31, 2023. We had no disposals for the period ended March 31, 2022.

6. Collaborative Arrangements and Revenue Recognition

Healios Collaboration

We have a licensing agreement with Healios to primarily develop and commercialize our cell therapy technologies for certain disease indications in Japan, pursuant to which we received nonrefundable license fee payments and are entitled to royalties on net sales. We also have the right to receive development and commercial milestone payments from Healios, subject to certain potential credits that have been negotiated from time-to-time and are associated with modifications to the arrangement. Healios is responsible for the development and commercialization of the licensed products in the licensed territory, and we provide certain services to Healios for which we are paid.

In August 2021, the Company and Healios entered into a Comprehensive Framework Agreement for Commercial Manufacturing and Ongoing Support, or the Framework Agreement, which provided for clarification under and modified the existing agreements between the parties. It also provided Healios with deferral of certain milestone payments. Under the Framework Agreement, the Company was entitled to payments for reimbursable services of which $0.7 million and $1.6 million are included in accounts receivable from Healios at March 31, 2023 and March 31, 2022, respectively.

In addition, under the Framework Agreement, the Company was entitled to a $3.0 million milestone payment from Healios and was obligated to pay Healios $1.1 million by December 31, 2022. In September 2022, we received $1.9 million from Healios, which represents the milestone payment net of amounts owed to Healios. Additionally, to assist Healios with the advancement of its ischemic stroke and acute respiratory distress syndrome (“ARDS”) programs in Japan, in September 2022, we granted to Healios, subject to the terms of the licensing agreement, a non-exclusive license to make and have made MultiStem for the treatment of ischemic stroke and ARDS worldwide solely for import for use in Japan. In connection with the execution of the Framework Agreement, the Cooperation Agreement was amended to extend certain customary standstill provisions until the conclusion of our 2023 annual meeting of stockholders.

In August 2021, we also issued two warrants (together, the “2021 Warrants”) to Healios in connection with the Framework Agreement to purchase up to a total of 400,000 shares of our common stock. The 2021 Warrants are being accounted for as consideration paid or payable to a customer according to Topic 606, *Revenue from Contracts with Customers*, and Topic 718, *Compensation Stock Compensation*, under which the recognition of such equity instruments is required at the time that the underlying performance conditions become probable or are satisfied. As of March 31, 2023, the 2021 Warrants have not been recorded as the underlying performance conditions have not been satisfied and are not yet considered probable. Refer to Note 8 for further information.

Healios has alleged that we are in material breach of our Framework Agreement for, among other things, not meeting our supply obligations and cooperation and assistance obligations. We strongly disagree with Healios’ allegations and will continue to work with Healios to try to resolve this dispute. However, there can be no assurance that we will be able to resolve this dispute without legal proceedings.

Healios Revenue Recognition

At the inception of the Healios arrangement and again each time that the arrangement has been modified, all material performance obligations were identified, which include (i) licenses to our technology, (ii) product supply services, and (iii) manufacturing services provided on Healios’ behalf.

Under the Framework Agreement, it was determined there was one performance obligation for services necessary for regulatory approvals, manufacturing readiness, and commercial launch in Japan. We determined the transaction price included estimated payments for reimbursable services to be performed by us for Healios and the $3.0 million milestone payment. We allocated the total transaction price to this one performance obligation. We began recognizing revenue in the third quarter of 2021 as the services were being performed. At March 31, 2023, the services related to this performance obligation are largely complete and consist of minimal close-out activities which are immaterial. During the three months ended March 31, 2023 we recognized no revenue associated with this performance obligation, compared to $2.8 million for three months ended March 31, 2022. We recognized no revenue for three months ended March 31, 2023 and March 31, 2022 from performance obligations satisfied in previous periods.

Accounts receivable from Healios

Accounts receivable from Healios are related to our contracts and are recorded when the right to consideration is unconditional at the amount that management expects to collect. Accounts receivable from Healios do not bear interest if paid when contractually due, and payments are generally due within thirty to forty-five days of invoicing.

Advance from Healios

In 2017, we amended the clinical trial supply agreement for the manufacturing of clinical product for TREASURE to clarify a cost-sharing arrangement. The proceeds from Healios that relate specifically to the cost-sharing arrangement may either (i) result in a reduction in the proceeds we receive from Healios upon the achievement of two potential milestones and an increase to a commercial milestone under the license agreement for stroke or (ii) be repaid to Healios at our election, as defined. The cost-sharing proceeds received are recognized in advance from Healios on the unaudited condensed consolidated balance sheets until the earlier of the milestones being achieved or such amounts being repaid to Healios at our election, at which time the culmination of the earnings process or the repayment will be complete.

Disaggregation of Revenues

We recognize product supply revenue at a point in time upon delivery, as defined in the applicable product supply contracts, while service revenue is recognized when earned over time. The following table presents our contract revenues disaggregated by timing of revenue recognition (in thousands):

	Three months ended March 31, 2023		Three months ended March 31, 2022	
	Point in Time	**Over Time**	Point in Time	Over Time
Contract Revenue from Healios				
Product supply revenue	**$ —**	**$ —**	$ —	$ —
Service revenue	**—**	**—**	—	2,912
Total disaggregated revenues	**$ —**	**$ —**	$ —	$ 2,912

7. Stock-Based Compensation

Our 2019 Equity and Incentive Compensation Plan (the "EICP") authorized at inception an aggregate of approximately 1,700,000 shares of our common stock for awards to employees, directors and consultants. The EICP authorizes the issuance of stock-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, 2023, a total of 627,290 shares (including 11,289 shares related to an expired incentive plan) of common stock have been issued under our equity incentive plans.

As of March 31, 2023, a total of 27,491 shares were available for issuance under our EICP, and stock-based awards representing 1,626,312 (including 28,404 shares related to an expired incentive plan) of common stock were outstanding. Additionally, inducement stock options granted outside of our equity incentive plans to purchase 429,500 shares of common stock were outstanding at March 31, 2023. For the three months ended March 31, 2023 and 2022, stock-based compensation expense was approximately $0.7 million and $1.4 million, respectively. At March 31, 2023, total unrecognized estimated compensation cost related to unvested stock-based awards was approximately $4.6 million, which is expected to be recognized by the end of 2026 using the straight-line method.

8. Stockholders' Equity and Warrants

At March 31, 2023 and March 31, 2022, we had 600,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock authorized. No shares of preferred stock have been issued as of March 31, 2023 and 2022.

August 2022 Securities Purchase Agreement

On August 15, 2022, the Company entered into a placement agency agreement with A.G.P./Alliance Global Partners ("A.G.P."), pursuant to which A.G.P. agreed to serve as exclusive placement agent for the issuance and sale of common stock and warrants. A.G.P. received a placement fee of approximately $0.8 million and approximately $0.1 million for the reimbursement of expenses.

On August 15, 2022, the Company entered into a securities purchase agreement (the "August 2022 Purchase Agreement") with an investor, pursuant to which the Company agreed to issue and sell, in a registered direct offering, (i) an aggregate of 1,200,000 shares of the Company's common stock, (ii) pre-funded warrants (the "August 2022 Pre-Funded Warrants") exercisable for an aggregate of 720,000 shares of common stock and (iii) warrants (the "August 2022 Common Warrants") exercisable for an aggregate of 1,920,000 shares of common stock, in combinations of one share of common stock or one August 2022 Pre-Funded Warrant and one August 2022 Common Warrant for a combined purchase price of $6.25 (less $0.0025 for any August 2022 Pre-Funded Warrant). Subject to certain ownership limitations, under the terms of the August 2022 Purchase Agreement, the August 2022 Pre-Funded Warrants were exercisable upon issuance, and the August 2022 Common Warrants were exercisable upon the six-month anniversary of issuance for a five-year period. Under the August 2022

Purchase Agreement, each August 2022 Pre-Funded Warrant was exercisable for one share of common stock at a price per share of $0.0025 and each August 2022 Common Warrant was exercisable for one share of common stock at a price per share of $6.385. The offering closed on August 17, 2022 and the Company received net proceeds of approximately $11.0 million, after giving effect to the payment of placement fees and expenses. On August 29, 2022, the August 2022 Pre-Funded Warrants were exercised in full and re-measured to fair value. Upon remeasurement and exercise, we recorded a gain of $0.8 million to adjust the warrant liability associated with the August 2022 Pre-Funded Warrants to fair value and reclassified the $3.8 million warrant liability to additional paid-in capital. The fair value adjustment is recorded in other income, net on the condensed consolidated statement of operations and comprehensive loss.

Pursuant to the August 2022 Purchase Agreement, in the event the Company proposes a future offering to sell shares of common stock during the twelve months following the closing date, the investor has the right to participate in each offering in an amount up to 30.0%.

On September 22, 2022, the Company entered into an amendment to the Purchase Agreement (the "August 2022 Purchase Agreement Amendment") with the investor to, among other things, (i) amend the August 2022 Common Warrants to be exercisable for a seven-year period after the six-month anniversary of the closing date, (ii) reduce the standstill period, (iii) reduce the term and the amount of the participation right, and (iv) require the investor, subject to certain conditions, to participate in future offerings to sell certain securities to investors primarily for capital raising purposes.

On September 22, 2022, in consideration of the August 2022 Purchase Agreement Amendment, and without receiving any cash proceeds, the Company issued to the investor additional warrants exercisable for 2,000,000 shares of common stock (the "September Warrants") at a price of $6.385 for a seven-year period after the six-month anniversary of the date of issuance thereof.

November 2022 Securities Purchase Agreement

On November 9, 2022, the Company entered into a placement agency agreement with A.G.P. pursuant to which A.G.P. agreed to serve as exclusive placement agent for the issuance and sale of common stock and warrants. A.G.P received a placement fee of approximately $0.4 million and approximately $0.1 million for the reimbursement of expenses.

On November 9, 2022, the Company entered into a securities purchase agreement (the "November 2022 Purchase Agreement") with investors, pursuant to which the Company agreed to issue and sell, in a public offering, (i) an aggregate of 3,927,275 shares of the Company's common stock, (ii) pre-funded warrants (the "November 2022 Pre-Funded Warrants") exercisable for an aggregate of 1,077,270 shares of common stock and (iii) warrants (the "November 2022 Common Warrants") exercisable for an aggregate of 10,009,090 shares of common stock, in combinations of one share of common stock or one November 2022 Pre-Funded Warrant and two November 2022 Common Warrants for a combined purchase price of $1.10 (less $0.0001 for any November 2022 Pre-Funded Warrant). Subject to certain ownership limitations, under the terms of the November 2022 Purchase Agreement, the November 2022 Pre-Funded Warrants and November 2022 Common Warrants were exercisable upon issuance. Under the November 2022 Purchase Agreement, each November 2022 Pre-Funded Warrant was exercisable for one share of common stock at a price per share of $0.0001 and each November 2022 Common Warrant is exercisable for one share of common stock at a price per share of $1.10 for a five-year period after the date of issuance. The offering closed on November 10, 2022 and the Company received net proceeds of approximately $5.0 million, after giving effect to the payment of placement fees and expenses. The November 2022 Pre-Funded Warrants were exercised in full at the closing.

The Company has assessed the Pre-Funded Warrants, the Common Warrants and the September Warrants (collectively, the "Warrants") for appropriate equity or liability classification pursuant to the Company's accounting policy as described in Note C, in our Annual Report on Form 10-K. The Warrants contain a provision pursuant to which the warrant holder has the option to receive cash in the event there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). The Warrants meet the definition of a derivative pursuant to ASC 815, Derivatives and Hedging and do not meet the derivative scope exception. As a result, the Warrants were initially recorded as liabilities and measured at fair value using the Black-Scholes valuation model. Issuance costs of $0.5 million were allocated to the Pre-Funded Warrants and Common Warrants and recorded in other income, net on the condensed consolidated statement of operations and comprehensive loss in the three ended September 30, 2022. The remaining issuance costs of $0.4 million were allocated to the Common Stock and recorded in additional paid-in capital. During the three months ended March 31, 2023, the Company recognized a net gain of 0.8 million for the fair value adjustment related to the warrant liabilities. As of March 31, 2023, the fair value of the warrant liabilities was $1.2 million.

April 2023 Securities Purchase Agreement

On April 18, 2023, the Company entered into a placement agency with A.G.P. pursuant to which A.G.P. agreed to serve as the exclusive placement agent for the issuance and sale of the Shares and Warrants. A.G.P. received a placement fee of approximately $0.2 million and approximately $0.1 million for the reimbursement of expenses.

On April 18, 2023, the Company entered into a securities purchase agreement (the "April 2023 Purchase Agreement") with investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering, (i) an aggregate of 2,315,000 shares of the Company's common stock and (ii) pre-funded warrants (the " April 2023 Pre-Funded Warrants") exercisable for an aggregate of 1,370,000 shares of Common Stock, together with warrants (the "Common Warrants" and, collectively with the April 2023 Pre-Funded Warrants, the "April Common Warrants") exercisable for an aggregate of 3,685,000 shares of the Company's common stock in a private placement, in combinations of one share or one April 2023 Pre-Funded Warrant and one April Common Warrant for a combined purchase price of $1.00. Subject to certain ownership limitations, the April 2023 Pre-Funded Warrants are exercisable upon issuance, and the April Common Warrants are exercisable upon the six-month anniversary of issuance. Each April 2023 Pre-Funded Warrant is exercisable for one share of common stock at a price per share of $0.0001 (as adjusted from time to time in accordance with the terms thereof) and does not expire. Each April 2023 Common Warrant is exercisable into one share of common stock at a price per share of $0.96 (as adjusted from time to time in accordance with the terms thereof) for a seven-year period after the six-month anniversary of the date of issuance. The offering closed on April 19, 2023, and received net proceeds of approximately $3.4 million, after giving effect to the payment of placement fees and expenses.

Healios 2021 Warrants

In August 2021, we issued the 2021 Warrants to Healios to purchase up to an aggregate of 400,000 shares of our common stock. One of the 2021 Warrants is for the purchase of up to 120,000 shares at an exercise price of $45.00 per share, subject to specified increases, and generally is only exercisable within 60 days of receipt of either conditional or full marketing approval from the Pharmaceuticals and Medical Devices Agency in Japan (the "PMDA") for the intravenous administration of MultiStem to treat patients who are suffering from acute respiratory distress syndrome. The other 2021 Warrant is for the purchase of up to 280,000 shares at an exercise price of $60.0 per share, subject to specified increases, and generally is only exercisable within 60 days of receipt of either conditional or full marketing approval from the PMDA for the intravenous administration of MultiStem to treat patients who are suffering from ischemic stroke. The 2021 Warrants may be terminated by us under certain conditions and have an exercise cap triggered at Healios' ownership of 19.9% of our common stock.

Equity Purchase Agreement

We previously had equity purchase agreements in place since 2011 with Aspire Capital that provided us the ability to sell shares to Aspire Capital from time to time. On May 12, 2022, we entered into an agreement (the "2022 Equity Facility") that included Aspire Capital's commitment to purchase up to an aggregate of $100.0 million of shares of our common stock over a defined timeframe. The terms of the 2022 Equity Facility were similar to the previous equity facilities with Aspire Capital. Our prior equity facility that was entered into in June 2021, or the 2021 Equity Facility, and includes Aspire Capital's commitment to purchase up to an aggregate of $100.0 million of shares of our common stock over a defined timeframe. The terms of the 2021 Equity Facility are similar to the previous equity facilities with Aspire Capital, and we filed a registration statement for the resale of 1,600,000 shares of our common stock in connection with the 2021 Equity Facility. Our prior equity facility that was entered into in 2019, that was fully utilized and terminated during the third quarter of 2021.

On July 6, 2022, Aspire Capital terminated the 2022 Equity Facility. Aspire Capital had the right to terminate the 2022 Equity Facility at the time or any time after any of the Company's then current executive officers ceased to be an executive officer or full-time employee of the Company, which right was triggered in connection with the departures of William Lehmann, former president and Chief Operating Officer, John Harrington, Former Executive Vice President and Chief Scientific Officer, and Ivor MacLeod, former Chief Financial Officer.

During quarter ended March 31, 2022, we sold 272,000 shares to Aspire Capital at average prices of $17.66 per share.

9. Fair Value Measurements

The carrying amounts of certain financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their respective fair values due to the short-term nature of such instruments.

Liabilities Measured at Fair Value on a Recurring Basis

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period. The requirement requires judgements to be made. Our Level 3 financial liabilities consist of the warrant liabilities for which there is no current market such that the determination of fair value requires judgement or estimation. Changes in fair value measurements categorized within Level 3 of the fair value hierarchy are analyzed each period based on changes in estimates or assumptions and recorded as appropriate. The Company uses the Black-Scholes option valuation model to value the Level 3 warrant liabilities at inception and on subsequent valuation dates. This model incorporates transaction detail such as the Company's stock price, contractual terms, maturing, risk free rates

as well as volatility. The unobservable input for the Level 3 warrant liabilities includes volatility, which is not significant to the fair value measurement of the warrant liabilities.

A reconciliation of the beginning and ending balances for the warrant liabilities which are measured at fair value on a recurring basis using significant unobservable inputs (Level 3) is as follows (in thousands):

	Warrant Liabilities
Balance December 31, 2022	**$ (534,000)**
Fair Value Adjustment - March 31, 2023	**(629,000)**
Balance March 31, 2023	**$ (1,163,000)**

10. Restructuring Charges

In June 2022, we announced a restructuring of our organization, including an approximate 70% reduction in our workforce. As part of the Plan we also announced changes to our executive team. Mr. Lehmann left the Company on May 31, 2022. Dr. Harrington and Mr. Macleod left the Company on June 30, 2022.

The Company's restructuring efforts are intended to preserve cash and reduce operating expenses going forward. In addition to the workforce reductions, the Company's restructuring efforts include the reduction of our internal research function, the decommissioning of certain equipment and pausing our manufacturing and process development efforts toward commercializing our MultiStem product candidate. We are attempting to negotiate payment terms with our primary contract manufacturing organization responsible for the manufacture of Multistem.

The following table sets forth certain details associated with the restructuring charges incurred in the three months ended March 31, 2023 and the obligations recorded for the expenses associated with the Plan (in thousands). It is anticipated the Plan will be completed by mid-2023.

	Balances December 31, 2022	Charges	Cash (payments)	Balances March 31, 2023
Employee severance and benefits	935	$ —	$ (370)	$ 565
Legal and professional fees	35	15	(23)	27
Other	15	—	—	15
	$ 985	$ 15	$ (393)	$ 607

The current portion of our restructuring accrual is included in accrued compensation and related benefits and accounts payable and there is no long-term portion of our restructuring accrual.

Restructuring charges are recorded general and administrative costs and expenses for the three months ended March 31, 2023.

11. Income Taxes

We have United States ("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. Substantially all of our deferred tax assets have been fully offset by a valuation allowance due to our cumulative losses. The carrying value of our deferred tax assets and liabilities is determined by the enacted U.S. corporate income tax rate. Consequently, any changes in the U.S. corporate income tax rate impacts the carrying value of our deferred tax assets and liabilities. Also, there are significant limitations on our ability to utilize our net operating loss and tax credit carryforwards under Section 382 of the Internal Revenue Code of 1986, as amended.

The utilization of net operating loss and tax credit carryforward generated prior to October 2012 (the "Section 382 Limited Attributes") is substantially limited under Section 382 of the Internal Revenue Code of 1986, as amended, (the "IRC"). We generated U.S. federal net operating loss carryforwards of $348.1 million, research and development tax credits of $24.4 million, and state and local net operating loss carryforwards of $140.3 million since 2012. Utilization of some of the federal and state net operating loss and tax credit carryforwards generated after October 2012 may be subject to additional annual limitations due to the "change in ownership" provisions of the IRC and similar state provisions. The annual limitations may result in the expiration of net operating losses and credits before utilization. The Company has not performed a Section 382 study subsequent to October 2012 as of March 31, 2023. We will update our analysis under Section 382 prior to using these attributes.

12. Subsequent Event

On April 13, 2023, we received notice from The Nasdaq Stock Market ("Nasdaq") that we had not regained compliance with the minimum market value of $35 million. On April 14, 2023, we filed our request for a hearing and our common stock is currently not being delisted pending the outcome of the hearing with Nasdaq Hearing Panel (the "Panel"). There can be no assurance that such appeal will be successful or that the Company will be able to regain compliance with the $35 million minimum market value or maintain compliance with other Nasdaq listing requirements. If the Company's appeal is denied or if it fails to regain compliance with Nasdaq's continued listing standards during any period granted by the Panel, the Common Stock will be subject to delisting from Nasdaq.

On April 17, 2023, the Company amended the August Warrants and the September Warrants to, among other things, reduce the exercise price to $0.96 per share with respect to 1,920,000 shares of Common Stock covered by the August Warrants and 1,760,000 shares of Common Stock covered by the September Warrants.

On April 18, 2023, the Company entered into a placement agency with A.G.P. pursuant to which A.G.P. agreed to serve as the exclusive placement agent for the issuance and sale of the Shares and Warrants. A.G.P. received a placement fee of approximately $0.2 million and approximately $0.1 million for the reimbursement of expenses.

On April 18, 2023, the Company entered into a securities purchase agreement (the "April 2023 Purchase Agreement") with investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering, (i) an aggregate of 2,315,000 shares of the Company's common stock and (ii) pre-funded warrants (the " April 2023 Pre-Funded Warrants") exercisable for an aggregate of 1,370,000 shares of Common Stock, together with warrants (the "Common Warrants" and, collectively with the April 2023 Pre-Funded Warrants, the "April Common Warrants") exercisable for an aggregate of 3,685,000 shares of the Company's common stock in a private placement, in combinations of one share or one April 2023 Pre-Funded Warrant and one April Common Warrant for a combined purchase price of $1.00. Subject to certain ownership limitations, the April 2023 Pre-Funded Warrants are exercisable upon issuance, and the April Common Warrants are exercisable upon the six-month anniversary of issuance. Each April 2023 Pre-Funded Warrant is exercisable for one share of common stock at a price per share of $0.0001 (as adjusted from time to time in accordance with the terms thereof) and does not expire. Each April 2023 Common Warrant is exercisable into one share of common stock at a price per share of $0.96 (as adjusted from time to time in accordance with the terms thereof) for a seven-year period after the six-month anniversary of the date of issuance. The offering closed on April 19, 2023, and received net proceeds of approximately $3.4 million, after giving effect to the payment of placement fees and expenses.

On April 21, 2023, we made the decision to and notified our landlord for the Stow facility that we surrendered possession of the property and returned the keys to the landlord. As a result of the impact this will have to operating results and cash flows, the Company has determined impairment indicators exist and will report any potential impairment charges within the quarterly report for quarter ending June 30, 2023, for assets including operating right of use assets.

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 condensed consolidated 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, 2022. Operating results are not necessarily indicative of results that may occur in future periods.

Overview and Recent Developments

We are a biotechnology company that is focused primarily in the field of regenerative medicine. Our MultiStem® (invimestrocel) cell therapy, a patented and proprietary allogeneic stem cell product candidate, is our lead platform product and is currently in clinical development. Our most advanced program is an ongoing Phase 3 clinical trial for the treatment of ischemic stroke. Our clinical development programs are focused on treating neurological conditions, 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.

Restructuring and Financial

In June 2022, we announced a restructuring of our organization, including an approximate 70% reduction in workforce. As part of the restructuring plan, we also announced changes to our executive team. William (B.J.) Lehmann, former President and Chief Operating Officer, left the Company on May 31, 2022. John Harrington, former Executive Vice President and Chief Scientific Officer, and Ivor Macleod, former Chief Financial Officer, left the Company on June 30, 2022.

In addition to the workforce reductions, in an effort to conserve cash and maintain adequate liquidity, we suspended operations in a number of areas including the reduction of our internal research function, plans for decommissioning certain equipment and suspending our manufacturing and process development efforts toward commercializing our MultiStem product candidate, if approved, as discussed below. We are currently unable to predict the duration of the suspension, and we plan to continue

limited operations until we obtain additional funding. Our current development activities are limited to progressing our pivotal Phase 3 clinical trial of MultiStem cell therapy for the treatment of ischemic stroke, referred to as MASTERS-2 and supporting the Phase 2 clinical trial evaluating MultiStem cell therapy for the early treatment of traumatic injuries and the subsequent complications that result following severe trauma being conducted by UTHealth, at the Memorial Hermann-Texas Medical Center, or UTHealth, in Houston, Texas one of the busiest Level 1 trauma centers in the United States.

As of May 11, 2023, we had accounts payable of $27.5 million, of which over 75% is owed to our primary contract manufacturer, that is currently due and we only had cash and cash equivalents of $3.6 million. We are actively working with our primary contract manufacturer to reach an agreement to address the outstanding accounts payable and continue our partnership going forward. The terms of any such agreement may entail our issuance of a convertible promissory note in exchange for a substantial reduction in the outstanding accounts payable, although there can be no assurance that we will be able to reach an agreement on terms acceptable to us or at all. To conserve cash, we have been managing our disbursements and working with our suppliers and service providers to address the outstanding accounts payable. In the near term, we will need to obtain significant capital through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to continue to fund our operations. However, there can be no assurance that we will be able to obtain such funding on terms acceptable to us, on a timely basis or at all, particularly in light of our current stock price and liquidity. If we are unable to obtain adequate financing, we likely would have to file for protection under the bankruptcy laws to continue to pursue potential transactions and conduct a wind down of our Company. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

Current Programs

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

- **Ischemic Stroke:** Our MASTERS-2 clinical trial is a randomized, double-blind, placebo-controlled clinical trial designed to enroll 300 patients in the United States and certain other international locations. The study is evaluating efficacy and safety of MultiStem cell therapy in patients who have suffered moderate to moderate-severe ischemic stroke. We initiated the study with a limited number of high-enrolling sites and have been bringing on additional sites over time in line with clinical product supply and clinical operations objectives.

  The MASTERS-2 study has received several regulatory designations and regulatory agreements including Special Protocol Assessment agreement, or SPA, Fast Track designation, Regenerative Medicine Advanced Therapy, or RMAT, designation and initial pediatric study plan, or iPSP agreement, from the U.S. Food and Drug Administration, or FDA, as well as a Final Scientific Advice positive opinion, Advanced Therapy Medicinal Product, or ATMP, quality certification and pediatric investigation plan, or PIP, agreement from the European Medicines Agency, or EMA.

  On March 21, 2023, we held a Type B meeting with the FDA to address proposed modifications to our primary and secondary endpoints for our MASTERS-2 clinical trial protocol. We proposed four modifications, all of which were accepted.

  - Changed the timing of the primary endpoint assessed by shift analysis in modified Rankin Scale, or mRS, score to Day 365, from Day 90.
  - Retained shift analysis in mRS score at Day 90 as a key secondary endpoint, along with other revised secondary endpoints.
  - Removed eligibility caps on concomitant reperfusion therapy to ensure the final study population is reflective of the current standard of care in the population eligible for this therapy
  - We may elect to have an independent statistician conduct an interim analysis to assess potential sample size adjustment.

  The fact that we were previously granted RMAT, Fast Track Designation and SPA agreement for the use of MultiStem enabled sponsors to work closely with the FDA and receive guidance on expediting the advancement of the designation program. We believe the proposed changes allow us to thoroughly evaluate the mechanisms through which MutliStem treatment can provide benefit to patients suffering an acute ischemic stroke. We believe this outcome more accurately reflects our belief that MultiStem's treatment effects extend beyond Day 90 and is better reflected with a Day 365 assessment of recovery.

  In addition, HEALIOS K.K., or Healios, our collaborator in Japan, conducted a clinical trial, TREASURE, evaluating the safety and efficacy of administration of MultiStem cell therapy for the treatment of ischemic stroke. In May 2022, Healios reported topline results for the TREASURE study. While the TREASURE trial did not reach statistical significance on its primary endpoint, Excellent Outcome at 90 days, it did demonstrate improvement in pre-

specified measures of functional "independence" and good outcomes, such as mRS < 2, Barthel Index > 95 and Global Recovery.

The proposed adjustments to our MASTERS-2 trial, based on our Type B meeting with the FDA, will impact the timing of enrollment completion. In addition, given our liquidity issues, we have postponed initiating new clinical sites. To complete enrollment of our MASTERS-2 trial, we are dependent on our primary contract manufacturer to release clinical product, which is currently on hold because of our outstanding liabilities. We are currently in discussions with our primary contract manufacturer regarding these outstanding liabilities as well as the supply of sufficient clinical product to complete the MASTERS-2 study. Due to these uncertainties, at this time, we are unable to predict when we will complete enrollment in our MASTERS-2 study, if at all. We will need to raise additional funding in order to complete our MASTERS-2 trial.

- **ARDS:** In January 2019 and January 2020, we announced summary results and one-year follow up results, respectively, from our exploratory clinical study of the intravenous administration of MultiStem cell therapy to treat patients who are suffering from acute respiratory distress syndrome, or ARDS, which is referred to as the MUST-ARDS study. The study results demonstrated a predictable and favorable tolerability profile. Importantly, there were lower mortality and greater ventilator-free days. or VFD, and ICU-free days in the MultiStem-treated patient group compared to the placebo group. Average quality-of-life outcomes were higher in the MultiStem group compared to placebo through one year. In April 2019, the MultiStem cell therapy received Fast Track designation for the treatment of ARDS, and in September 2020, RMAT designation was received for the same program. In April 2020, in response to the COVID-19 pandemic, the FDA authorized the initiation of a Phase 2/3 pivotal study to assess the safety and efficacy of MultiStem therapy in subjects with moderate to severe ARDS, or the MACOVIA study. The MACOVIA study features an open-label lead-in dose escalation portion of the study, followed by double-blinded, randomized, placebo-controlled study cohorts, and the study is designed to enroll up to approximately 400 patients at leading pulmonary critical care centers throughout the United States. During 2021, we amended the protocol with the FDA to adjust the scope of the MACOVIA study to include subjects with ARDS induced by pathogens other than COVID-19. We received approval from the FDA to use MultiStem product manufactured with our bioreactor-based technology in the study, an important product development milestone. We have suspended initiating new sites and enrolling patients in the Phase 2 part of the MACOVIA trial prior to enrolling patients using our bioreactor-based technology. We now have data evaluating two different dosing levels of MultiStem. Analysis of this data will help inform the design of the next phase of the trial once we are ready to restart utilizing bioreactor manufactured MultiStem product. However, we are currently focusing resources on our MASTERS-2 study. Until we receive additional financing or establish a partnership to move forward with the next phase of the study, the MACOVIA trial has been suspended.

  Further, in 2019, Healios initiated the ONE-BRIDGE study in Japan for patients with pneumonia-induced and COVID-induced ARDS and, in August 2021, Healios reported top-line data from the ONE-BRIDGE study. We and Healios have conducted thorough analyses of the data from the MUST-ARDS and ONE-BRIDGE studies. The studies had comparable patient populations receiving the same MultiStem dose amount shortly following an ARDS diagnosis. Between the studies, excluding the COVID-ARDS cohort in the ONE-BRIDGE study, 60 ARDS subjects were enrolled in the studies, 40 receiving MultiStem treatment and the remaining 20 receiving placebo or standard of care. On a pooled basis, strong trends were observed in VFD, survival, improved quality-of-life and reduction of key inflammatory biomarkers. For example, MultiStem-treated subjects had, on average, 5.5 more VFD in the first 28 days following diagnosis than non-treated subjects ($p=0.07$) and, on a median basis, 10.5 more VFD. In April 2022, Healios announced that, while the PMDA did not disagree with the efficacy and safety conclusions of the ONE-BRIDGE study, the PMDA advised Healios that additional supporting data is necessary for application for approval of MultiStem treatment for the ARDS indication in Japan. As a result of the guidance from the PMDA, Healios disclosed that it will continue discussions with PMDA.

- **Trauma:** In April 2020, the FDA authorized the initiation of a Phase 2 clinical trial evaluating MultiStem cell therapy for the early treatment of traumatic injuries and the subsequent complications that result following severe trauma. The trial is being conducted by UTHealth, at the Memorial Hermann-Texas Medical Center in Houston, Texas, one of the busiest Level 1 trauma centers in the United States. This study is being supported under a grant awarded to the McGovern Medical School at UTHealth from the Medical Technology Enterprise Consortium, and the Memorial Hermann Foundation is providing additional funding. We are providing the investigational clinical product manufactured with our bioreactor-based technology for the trial as well as regulatory and operational support. We will need to resolve our outstanding liabilities with our primary contract manufacturing organization to receive sufficient clinical product to complete enrollment in this study.

Although some of our collaborators continue to engage in preclinical development and evaluation of MultiStem cell therapy in other indications for human health, we have suspended all of our own internal research efforts at this time to conserve cash and decrease expenses.

In connection with our restructuring plan, in the second quarter of 2022, we paused work performed at our Belgian subsidiary, ReGenesys, which was evaluating our cell therapy for use in treating disease and conditions in the animal health segment. We are exploring opportunities to out-license this program. The restructuring also resulted in the closing of Athersys' ReGenesys facility in Belgium at the end of 2022, although we are still actively exploring potential business development partners for the animal health program.

On April 21, 2023, we made the decision to and notified our landlord for the Stow facility that we surrendered possession of the property and returned the keys to the landlord. As a result of the impact this will have to operating results and cash flows, the Company has determined impairment indicators exist and will report any potential impairment charges within the quarterly report for quarter ending June 30, 2023, for assets including operating right of use assets.

We have agreements with our primary contract manufacturing organization for the manufacture of our MultiStem product candidate to supply our planned and ongoing clinical trials. In June 2022, we suspended these agreements and are attempting to negotiate payment terms. There can be no guarantee, however, that we will be successful in such negotiations. Under the terms of these agreements, we currently owe this contract manufacturing organization approximately $21.5 million and have significant future financial commitments to support our bioreactor manufacturing initiatives. We also were engaged in process development initiatives intended to increase manufacturing scale, reduce production costs and enhance process controls and product quality. These initiatives and the related investments were meant to enable us to meet potential commercial demand in the event of eventual regulatory approval. We have also paused these initiatives as we work to obtain additional funding. Additionally, as part of our cost cutting initiatives, we have scaled back all activities intended to enable MultiStem commercialization, e.g., product branding, product reimbursement and marketing strategies.

Financial

We have entered into a series of agreements with Healios, our collaborator in Japan and one of our largest stockholder. Under the collaboration that began in 2016, Healios is responsible for the development and commercialization of the MultiStem product for the licensed fields in the licensed territories, and we provide services to Healios for which we are compensated. Each license agreement with Healios has defined economic terms, and we may receive success-based milestone payments, some of which may be subject to credits. In August 2021, we entered into a Comprehensive Framework Agreement for Commercial Manufacturing and Ongoing Support, or the Framework Agreement, with Healios, which provides for resolution of certain issues under the existing agreements between the parties and reframes our collaboration to set the stage for productive efforts as Healios and our collaboration move towards commercialization of MultiStem in Japan. It also provides Healios with deferral of certain milestone payments during the expensive initial commercial launch period. Also, we are entitled to receive tiered royalties on net product sales, as defined in the license agreements.

On August 15, 2022, the Company entered into a placement agency agreement with A.G.P./Alliance Global Partners, or A.G.P., pursuant to which A.G.P. agreed to serve as exclusive placement agent for the issuance and sale of common stock and warrants. A.G.P received a placement fee of approximately $0.8 million and approximately $0.1 million for the reimbursement of expenses.

On August 15, 2022, the Company entered into a securities purchase agreement, or the August Purchase Agreement, with an investor, pursuant to which the Company agreed to issue and sell, in a registered direct offering, (i) an aggregate of 1,200,000 shares of the Company's common stock, (ii) pre-funded warrants, or the August Pre-Funded Warrants, exercisable for an aggregate of 720,000 shares of common stock and (iii) warrants, or the August Common Warrants, exercisable for an aggregate of 1,920,000 shares of common stock, in combinations of one share of common stock or one August Pre-Funded Warrant and one August Common Warrant for a combined purchase price of $6.25 (less $0.0025 for any August Pre-Funded Warrant). Subject to certain ownership limitations, under the terms of the August Purchase Agreement, the August Pre-Funded Warrants were exercisable upon issuance, and the August Common Warrants were exercisable upon the six-month anniversary of issuance for a five- year period. Under the August Purchase Agreement, each August Pre-Funded Warrant was exercisable for one share of common stock at a price per share of $0.0025 and each Common Warrant is exercisable for one share of common stock at a price per share of $6.385. The offering closed on August 17, 2022, and the Company received net proceeds of approximately $11.0 million, after giving effect to the payment of placement fees and reimbursed expenses. On August 29, 2022, the August Pre-Funded Warrants were exercised in full.

On September 22, 2022, the Company entered into an amendment to the August Purchase Agreement, or the Purchase Agreement Amendment, with the investor to, among other things, (i) amend the August Common Warrants to be exercisable for a seven-year period after the six-month anniversary of the closing date, (ii) reduce the standstill period, (iii) reduce the term and the amount of the participation right, and (iv) require the investor, subject to certain conditions, to participate in future offerings to sell certain securities to investors primarily for capital raising purposes.

On September 22, 2022, in consideration of the Purchase Agreement Amendment, and without receiving any cash proceeds, the Company issued to the investor additional warrants exercisable for 2,000,000 shares of common stock, or the September Common Warrants, at a price of $6.385 for a seven-year period after the six-month anniversary of the date of issuance thereof.

On April 17, 2023, the Company amended the August Warrants and the September Warrants to, among other things, reduce the exercise price to $0.96 per share with respect to 1,920,000 shares of Common Stock covered by the August Warrants and 1,760,000 shares of Common Stock covered by the September Warrants.

On November 9, 2022, the Company entered into a placement agency agreement with A.G.P. pursuant to which A.G.P. agreed to serve as exclusive placement agent for the issuance and sale of common stock and warrants. A.G.P. received a placement fee of approximately $0.4 million and approximately $0.1 million for the reimbursement of expenses.

On November 9, 2022, the Company entered into a securities purchase agreement, or the November Purchase Agreement, with investors, pursuant to which the Company agreed to issue and sell, in a public offering, (i) an aggregate of 3,927,275 shares of the Company's common stock, (ii) pre-funded warrants, or the November Pre-Funded Warrants, exercisable for an aggregate of 1,077,270 shares of common stock and (iii) warrants, or the November Common Warrants, exercisable for an aggregate of 10,009,090 shares of common stock, in combinations of one share of common stock or one November Pre-Funded Warrant and two November Common Warrants for a combined purchase price of $1.10 (less $0.0001 for any November Pre-Funded Warrant). Subject to certain ownership limitations, under the terms of the November Purchase Agreement, the November Pre-Funded Warrants and the November Common Warrants were exercisable upon issuance. Under the November Purchase Agreement, each November Pre-Funded Warrant was exercisable for one share of common stock at a price per share of $0.0001 and each November Common Warrant is exercisable for one share of common stock at a price per share of $1.10 for a five-year period after the date of issuance. The offering closed on November 10, 2022, and the Company received net proceeds of approximately $5.0 million, after giving effect to the payment of placement fees and reimbursed expenses. The November Pre-Funded Warrants were exercised in full at the closing.

On April 18, 2023, the Company entered into a securities purchase agreement, or the April 2023 Purchase Agreement, with investors, pursuant to which the Company agreed to issue and sell, in a public offering, (i) an aggregate of 2,315,000 shares of the Company's common stock and (ii) pre-funded warrants, or the April 2023 Pre-Funded Warrants, exercisable for an aggregate of 1,370,000 shares of Common Stock, together with warrants, or the April 2023 Common Warrants and, collectively with the April 2023 Pre-Funded Warrants, the April 2023 Warrants, exercisable for an aggregate of 3,685,000 shares of common stock in a private placement, in combinations of one share or one April 2023 Pre-Funded Warrant and one April 2023 Common Warrant for a combined purchase price of $1.00, in a private placement. Subject to certain ownership limitations, the April 2023 Pre-Funded Warrants are exercisable upon issuance, and the April 2023 Common Warrants are exercisable upon the six-month anniversary of issuance. Each April 2023 Pre-Funded Warrant is exercisable for one share of common stock at a price per share of $0.0001 (as adjusted from time to time in accordance with the terms thereof) and does not expire. Each April 2023 Common Warrant is exercisable into one share of common stock at a price per share of $0.96 (as adjusted from time to time in accordance with the terms thereof) for a seven-year period after the six-month anniversary of the date of issuance. The offering closed on April 19, 2023, and received net proceeds of approximately $3.4 million, after giving effect to the payment of placement fees and expenses.

In August 2021, we entered into the Framework Agreement with Healios, which provides for resolution of certain issues under the existing agreements between the parties. It also provides Healios with the deferral of certain milestone payments during the expensive initial commercial launch period. Under the Framework Agreement, we were entitled to a milestone payment in the amount of $3.0 million. Additionally, under the terms of the Framework Agreement, we were obligated to pay Healios $1.1 million by December 31, 2022. In September 2022, we received $1.9 million from Healios, which represents the milestone payment net of amounts owed to Healios. Additionally, to assist Healios with the advancement of its ischemic stroke and ARDS programs in Japan, in September 2022, we granted to Healios, subject to the terms of the licensing agreement, a non-exclusive license to make and have made MultiStem for the treatment of ischemic stroke and ARDS worldwide solely for import into Japan for use in Japan.

Healios has alleged that we are in material breach of our Framework Agreement for, among other things, not meeting our supply obligations and cooperation and assistance obligations. We strongly disagree with Healios' allegations and will continue to work with Healios to try to resolve this dispute. However, there can be no assurance that we will be able to resolve this dispute without legal proceedings.

Results of Operations

Since our inception, our revenues have consisted of license fees, contract revenues, royalties and milestone payments from our collaborators, and grant proceeds. We have not derived revenue from our commercial sale of therapeutic products to date since we are in clinical development. In prior periods, research and development expenses consisted primarily of external clinical and preclinical study fees, manufacturing and process development costs, salaries and related personnel costs, legal expenses resulting from intellectual property prosecution processes, facility costs, restructuring charges and laboratory supply and reagent costs. We expense research and development costs as they are incurred. General and administrative expenses consist primarily of salaries and related personnel costs, professional fees, restructuring charges and other corporate expenses. We expect to continue to incur substantial losses through at least the next several years.

Three Months Ended March 31, 2023 and 2022

Revenues. Revenues for the three months ended March 31, 2023 were $0.0 million compared to $2.9 million for the three months ended March 31, 2022. The revenues are primarily associated with services provided to Healios under the Framework Agreement. At September 30, 2022, the services under the Framework Agreement are largely complete, and are limited to minimal close-out activities. Our collaboration revenues will fluctuate from period-to-period based on the services provided under our arrangement with Healios.

Research and Development Expenses. Research and development expenses decreased to $4.5 million for the three months ended March 31, 2023 from $20.9 million for the comparable period in 2022. The $16.4 million decrease is due to our restructuring plan which resulted in reduced salaries and benefits of $3.8 million, internal research supplies of $1.9 million, manufacturing costs of $9.5 million, outside services of $0.9 million and decreases in other research and development costs of $0.3 million. Our clinical development, clinical manufacturing and manufacturing process development expenses vary over time based on the timing and stage of clinical trials underway, manufacturing campaigns for clinical trials and manufacturing process development projects. These variations in activity level may also impact our accounts payable, accrued expenses, prepaid expenses and deposits 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 decreased to $2.8 million for the three months ended March 31, 2023, from $4.1 million for the comparable period in 2022. The decrease is primarily related to restructuring costs. We expect our general and administrative expenses to continue to decrease in connection with our restructuring plan.

Depreciation. Depreciation expense was $0.1 million for the three months ended March 31, 2023 and $0.2 million for the comparable period in 2022. The decrease is due to the sale of equipment associated with the decommissioning of certain equipment as a result of our restructuring plan.

Other Income, net. Other income, net, was $(0.5) million for both the three months ended March 31, 2023 and 2022.

Liquidity and Capital Resources

Our primary source of liquidity is our cash balance. At March 31, 2023, we had $3.1 million in cash and cash equivalents. We have primarily financed our operations through business collaborations, grant funding and equity financing. 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.

Our current capital requirements depend on a number of factors, including progress in our MASTERS-2 trial, additional external costs, such as payments to contract research organizations and contract manufacturing organizations, personnel costs and the costs of filing and prosecuting patent applications and enforcing patent claims. Furthermore, continued delays in product supply caused by nonpayment to our primary contract manufacturer for our clinical trials may impact the timing and cost of such studies.

We are entitled to receive potential milestones payments, subject to certain credits, and royalties from Healios under our licensed programs. Under the Framework Agreement, in September 2022, we received $1.9 million from Healios which represents a milestone payment in the amount of $3.0 million, net of amounts payable to Healios. We invoice Healios for certain manufacturing support services. Payments from Healios may be used by Healios to offset milestone payments that may become due in the future.

As of May 11, 2023, we had accounts payable of $27.5 million that is currently due, and we only had cash and cash equivalents of $3.6 million. To conserve cash, we have been delaying payments to most of our suppliers and service providers. In the near term, we will need to obtain significant capital through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to continue to fund our operations. However, there can be no assurance that we will be able to obtain such funding on terms acceptable to us, on a timely basis or at all, particularly in light of our current stock price and liquidity. If we are unable to obtain funding, we may be required to further delay, reduce or eliminate our MultiStem product candidate approval and commercialization efforts, which would adversely affect our business prospects, and we likely will be unable to continue operations. If we are unable to obtain adequate financing, we likely would have to file for protection under the bankruptcy laws to continue to pursue potential transactions and conduct a wind down of our Company. If we decide to dissolve and liquidate our assets or to seek protection under the bankruptcy laws, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources will be available for distributions to stockholders.

We have prepared our unaudited condensed consolidated financial statements on a going concern basis, which assumes that we will realize our assets and satisfy our liabilities in the normal course of business. However, we have incurred losses since inception of our operations in 1995, have negative operating cash flows, including in each of the last three years, and had an accumulated deficit of $663.7 million at March 31, 2023. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, manufacturing and process development, acquisition and licensing costs, and general and administrative costs associated with our operations. These circumstances raise substantial doubt about our ability to continue as a going concern. The accompanying unaudited condensed financial statements do not include any adjustments to reflect the possible future effect on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning our ability to continue as a going concern.

While we believe our restructuring plan will reduce costs and alleviate to some extent the conditions that raise substantial doubt, these plans are not entirely within our control and cannot be assessed as being probable of occurring. For the foreseeable future, our ability to continue our operations is dependent upon our ability to obtain additional capital, which may not be available to us on acceptable terms, on a timely basis or at all.

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 $6.0 million for the three months ended March 31, 2023 compared to $20.2 million for the three months ended March 31, 2022. 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 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 receivable, accounts payable, accrued expenses, prepaid expenses and deposits balances from period to period.

Net cash provided in investing activities was $0.1 million for the three months ended March 31, 2023 compared to cash used of $0.2 million for the three months ended March 31, 2022. The fluctuations over the periods were due to the timing of additions to property and equipment primarily for our manufacturing process development activities.

Financing activities used cash of $0.1 million and provided $4.7 million for the three months ended March 31, 2023 and 2022, respectively. The decrease from the comparable period is primarily related to the termination of our equity purchase agreement with Aspire Capital in July 2022. Also included in financing activities for the three months ended March 31, 2023 and March 31, 2022 are shares retained for withholding tax payments on stock-based awards.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Critical Accounting Policies and Management Estimates

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

Stock-Based Compensation

We determine the estimated fair value of each stock option on the date of grant using the Black-Scholes option-pricing model. The expected term of stock options granted represent the period of time that stock option grants are expected to be outstanding and subsequent to June 2020, is determined based on our historical experience and patterns. Prior to June 2020, we used the "simplified" method to calculate the expected term of option grants. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the stock option at the time of the grant. We determine volatility by using our historical stock volatility. We account for forfeitures as they occur. We have never paid or declared dividends or paid dividends on our common stock and have no plans to do so in the foreseeable future. Changes in these assumptions may lead to variability with respect to the amount of stock compensation expense we recognize related to stock options.

Additionally, stock-based compensation for an award with a performance condition requires the judgement of management. For such awards, stock-based compensation is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized.

Fair Value of Warrant Liabilities

In August 2022, we entered into the August Purchase Agreement, which resulted in the issuance of common stock, the August Pre-Funded Warrants, and The August Common Warrants, exercisable for a specified price, starting after a specified period of time, and for a specified period of time after the deal had closed. The August 2022 Warrants meet the definition of a derivative pursuant to ASC 815, *Derivatives and Hedging,* and do not meet the derivative scope exception. As a result, the August 2022 Warrants were initially recorded as liabilities and measured at fair value using the Black-Scholes valuation model. The warrants are adjusted to fair value at the end of each quarter. The adjustment to fair value is recorded in Other Income in the Statement of Operations and Comprehensive Loss

We use a valuation expert to help us determine the fair value of the August 2022 Warrants, using the Black-Scholes model to estimate the fair value of the August 2022 Warrants. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the common warrants at the time of the issuance. We determine volatility by using our historical stock volatility. We have never paid or declared dividends or paid dividends on our common stock and have no plans to do so in the foreseeable future. Changes in these assumptions may lead to variability with respect to the amount of gain or loss in fair value of the August 2022 Warrants.

The issuance of the November Common Warrants was deemed to be equity accounting and no estimates are required for this transaction.

Refer to Note C, *Accounting Policies,* for a discussion of our accounting policies and recently issued accounting standards.

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 timing of initiation of new clinical sites and patient enrollment in our clinical trials, the expected timetable for development of our product candidates, our growth strategy, and our future financial performance, including our operations, economic performance, financial condition, prospects, and other future events. We have attempted to identify forward-looking statements by using such words as “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “should,” “suggest,” “will,” or other similar expressions. These forward-looking statements are only predictions and are largely based on our current expectations. These forward-looking statements appear in a number of places in this Annual Report.

In addition, a number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements. Some of the more significant known risks that we face are the risks and uncertainties inherent in the process of discovering, developing, and commercializing products that are safe and effective for use as 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 in the near term and long term, including our ability to obtain funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, on terms acceptable to us or at all, and to continue as a going concern;
- our ability to successfully resolve the payment issues with our primary contract manufacturer and gain access to our clinical product;
- our collaborators’ ability and willingness to continue to fulfill their obligations under the terms of our collaboration agreements and generate sales related to our technologies;
- the possibility of unfavorable results from ongoing and additional clinical trials involving MultiStem;
- the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in an early stage clinical trial may not be predictive of results in later stage or large scale clinical trials;
- our ability to regain compliance with the requirement to maintain a minimum market value of listed securities of $35 million as set forth in Nasdaq Listing Rule 5550(b)(2);
- the timing and nature of results from MultiStem clinical trials, including the MASTERS-2 Phase 3 clinical trial evaluating the administration of MultiStem for the treatment of ischemic stroke;

- our ability to meet milestones and earn royalties under our collaboration agreements, including the success of our collaboration with Healios;
- the success of our MACOVIA clinical trial evaluating the administration of MultiStem for the treatment of ARDS induced by COVID-19 and other pathogens, and the MATRICS-1 clinical trial being conducted with UT Health evaluating the treatment of patients with serious traumatic injuries;
- the availability of product sufficient to meet our clinical needs and potential commercial demand following any approval;
- 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, contamination, operational restrictions due to COVID-19 or other public health emergencies, labor constraints, regulatory issues or other factors that could negatively impact our trials and the trials of our collaborators;
- uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for neurological, inflammatory and immune, cardiovascular and other critical care 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;
- the success of our efforts to enter into new strategic partnerships and advance our programs;
- our possible inability to execute our strategy due to changes in our industry or the economy generally;
- changes in productivity and reliability of suppliers;
- the success of our competitors and the emergence of new competitors; and
- the risks mentioned elsewhere in this Annual Report on Form 10-K under Item 1A, "Risk Factors." and our other filings with the SEC.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, operating results, growth strategy and liquidity. 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. You should not place undue reliance on these forward-looking statements because such statements speak only as of the date when made.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.

On April 13, 2023, we received notice from The Nasdaq Stock Market ("Nasdaq") that we had not regained compliance with the minimum market value of $35 million. On April 14, 2023, we filed our request for a hearing and our common stock is currently not being delisted pending the outcome of the hearing with Nasdaq Hearing Panel ("the panel"). There can be no assurance that such appeal will be successful or that the Company will be able to regain compliance with the $35 million minimum market value or maintain compliance with other Nasdaq listing requirements. If the Company's appeal is denied or if it fails to regain compliance with Nasdaq's continued listing standards during any period granted by the Panel, the Common Stock will be subject to delisting from Nasdaq.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There were no material changes in our exposure to market risk since the disclosure included in 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, 2022.

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 interim Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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 interim Chief Financial Officer 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(f) and 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors.

In addition to the other information set forth elsewhere in this Quarterly Report on Form 10-Q, you should carefully consider the risk factors set forth below and the other risk factors discussed in Part I, Item 1A "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2022. Those factors, if they were to occur, could cause our actual results to differ materially from those expressed in our forward-looking statements in this report, and materially adversely affect our financial condition or future results. Although we are not aware of any other factors that we currently anticipate will cause our forward-looking statements to differ materially from our future actual results, or materially affect the Company's financial condition or future results, additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition and/or operating results.

We are not currently in compliance with Nasdaq's continued listing requirements. If we are unable to comply with Nasdaq's continued listing requirements, our Common Stock could be delisted, which could affect the price of our Common Stock and liquidity and reduce our ability to raise capital.

Our Common Stock is currently listed on The Nasdaq Capital Market. The Nasdaq Capital Market has established certain quantitative criteria and qualitative standards that companies must meet to remain listed for trading on this market.

On October 14, 2022, we received a written notice (the "Notice") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") that we are not in compliance with the requirement to maintain a minimum market value of listed securities of $35 million, as set forth in Nasdaq Listing Rule 5550(b)(2) (the "Market Value Standard") because the market value of the Common Stock was below $35 million for 30 consecutive business days. The Notice does not impact the listing of the Common Stock on the Nasdaq Capital Market at this time.

The Notice provided that, in accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has a period of 180 calendar days from the date of the Notice, or until April 12, 2023, to regain compliance under the Market Value Standard. During this period, the Common Stock will continue to trade on the Nasdaq Capital Market. However, there can be no assurance that the Company will be able to regain compliance with the rule or will otherwise be in compliance with other Nasdaq listing criteria. If we are unable to regain compliance, Nasdaq may make a determination to delist our Common Stock. Any delisting of our Common Stock could adversely affect the market liquidity of our Common Stock and the market price of our Common Stock could decrease. Furthermore, if our Common Stock were delisted it could adversely affect our ability to obtain financing for the continuation of our operations and our ability to attract and retain employees by means of equity compensation and/or result in the loss of confidence by investors.

Item 6. Exhibits.

Exhibit No.	Description
3.1	Certificate of Amendment to Certificate of Incorporation, as amended, of Athersys, Inc (incorporated herein by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on August 29, 2022).
4.1	Form of Pre-Funded Warrant (incorporated herein by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on April 18, 2023).
4.2	Form of Warrant (incorporated herein by reference to Exhibit 4.2 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on April 18, 2023).
4.3	Form of Warrant Amendment No. 1 to Common Stock Purchase Warrant(incorporate herein by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on April 18, 2023).
4.4	Form of Warrant Amendment No. 2 to Common Stock Purchase Warrant (incorporate herein by reference to Exhibit 4.2 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on April 18, 2023).
10.1	Form of Securities Purchase Agreement, dated as of April 18, 2023, between the Company and each purchaser named in the signature pages thereto (incorporated herein by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K (Commission No. 001-33876) filed with the Commission on April 18, 2023).
31.1	Certification of Daniel Camardo,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 Kasey Rosado, interim Chief Financial Officer, 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 Daniel Camardo, Chief Executive Officer, and Kasey Rosado, interim Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Athersys' Quarterly Report on Form 10-Q for the period ended March 31, 2023, are formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets; (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss; (iii) the Condensed Consolidated Statements of Stockholders' Equity; (iv) the Condensed Consolidated Statements of Cash Flows; (v) Notes to Unaudited Condensed Consolidated Financial Statements; and (vi) document and entity information.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and contained in Exhibit 101).

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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 15, 2023

/s/ Daniel Camardo

Daniel Camardo
Chief Executive Officer and Duly Authorized Officer

/s/ Kasey Rosado

Kasey Rosado
Interim Chief Financial Officer

EXHIBIT 31.1

CERTIFICATIONS

I, Daniel Camardo., certify that:

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

Date: May 15, 2023

/s/ Daniel Camardo
Daniel Camardo
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATIONS

I, Kasey Rosado, certify that:

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

Date: May 15, 2023

/s/ Kasey Rosado
Kasey Rosado
Interim Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Quarterly Report of Athersys, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

Date: May 15, 2023

/s/ Daniel Camardo
Name: Daniel Camardo
Title: Chief Executive Officer

/s/ Kasey Rosado
Name: Kasey Rosado
Title: Interim Chief Financial Officer

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