

ATHERSYS, INC / NEW
Form 10-Q
November 10, 2008

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2008
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____.
Commission file number: 001-33876

Athersys, Inc.

(Exact name of registrant as specified in its charter)

Delaware

20-4864095

*(State or other jurisdiction
of incorporation or organization)*

(I.R.S. Employer Identification No.)

3201 Carnegie Avenue, Cleveland, Ohio

44115-2634

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: **(216) 431-9900**

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The number of outstanding shares of the registrant's common stock, \$0.001 par value, as of November 1, 2008 was 18,927,988.

ATHERSYS INC.
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Athersys, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)

	September 30, 2008 (Unaudited)	December 31, 2007 (Note)
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,748	\$ 13,248
Available-for-sale securities	17,980	22,477
Accounts receivable	947	836
Receivable from Angiotech	243	63
Investment interest receivable	215	262
Deposits	740	163
Prepaid expenses and other	597	394
 Total current assets	 35,470	 37,443
 Available-for-sale securities	 1,988	 13,850
Deposits	144	100
Note receivable, net	43	86
Equipment, net	715	387
Accounts receivable, net		42
Equity investments	317	317
 Total assets	 \$ 38,677	 \$ 52,225
 Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 1,959	\$ 1,011
Accrued compensation and related benefits	194	71
Accrued clinical trial costs	98	735
Accrued expenses and other	775	993
Current portion of long-term debt, net		1,784
 Total current liabilities	 3,026	 4,594
 Stockholders equity:		
Preferred stock, at stated value; 10,000,000 shares authorized, and no shares issued and outstanding at September 30, 2008 and December 31, 2007		
Common stock, \$0.001 par value; 100,000,000 shares authorized, and 18,927,988 shares issued and outstanding at September 30, 2008 and December 31, 2007	19	19
Additional paid-in capital	209,443	208,039
Accumulated other comprehensive (loss) income	(53)	52

Accumulated deficit	(173,758)	(160,479)
Total stockholders' equity	35,651	47,631
Total liabilities and stockholders' equity	\$ 38,677	\$ 52,225

Note: The balance sheet at December 31, 2007 has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by U.S. generally accepted accounting principles for complete financial statements.

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Revenues				
License fees	\$ 885	\$ 500	\$ 1,728	\$ 1,123
Grant revenue	393	360	1,118	1,339
Total revenues	1,278	860	2,846	2,462
Costs and expenses				
Research and development	4,730	4,215	12,782	11,569
General and administrative	1,246	2,113	4,108	6,218
Depreciation	49	71	158	226
Total costs and expenses	6,025	6,399	17,048	18,013
Loss from operations	(4,747)	(5,539)	(14,202)	(15,551)
Other income	22	500	42	2,000
Interest income	232	724	974	946
Interest expense		(124)	(93)	(1,167)
Accretion of premium on convertible debt				(456)
Net loss	\$ (4,493)	\$ (4,439)	\$ (13,279)	\$ (14,228)
Preferred stock dividends	\$	\$	\$	\$ (659)
Deemed dividend resulting from induced conversion of convertible preferred stock	\$	\$	\$	\$ (4,800)
Net loss attributable to common stockholders	\$ (4,493)	\$ (4,439)	\$ (13,279)	\$ (19,687)
Basic and diluted net loss per common share attributable to common stockholders	\$ (0.24)	\$ (0.23)	\$ (0.70)	\$ (2.44)
Weighted average shares outstanding, basic and diluted	18,927,988	18,927,988	18,927,988	8,075,763
See accompanying notes to unaudited condensed consolidated financial statements.				

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

	Nine months ended	
	September 30,	
	2008	2007
Operating activities		
Net loss	\$ (13,279)	\$ (14,228)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	158	226
Gain on sale of fixed assets	(24)	
Accretion of premium on convertible debt		456
Stock-based compensation	1,404	4,718
Provision on note receivable	43	193
Expense related to warrants issued to lenders	16	459
Amortization of premium (discount) on available-for-sale securities and other	(44)	7
Changes in operating assets and liabilities:		
Accounts receivable	(69)	375
Receivable from Angiotech	(180)	
Prepaid expenses and other assets	(777)	157
Accounts payable and accrued expenses	216	553
Net cash used in operating activities	(12,536)	(7,084)
Investing activities		
Purchase of available-for-sale securities	(21,701)	(15,002)
Maturities of available-for-sale securities	37,999	
Proceeds from sale of fixed assets	24	
Purchase of equipment	(486)	(66)
Net cash provided by (used in) investing activities	15,836	(15,068)
Financing activities		
Principal payments on debt	(1,800)	(2,576)
Proceeds from convertible promissory note		5,000
Proceeds from issuance of common stock, net		58,494
Net cash (used in) provided by financing activities	(1,800)	60,918
Increase in cash and cash equivalents	1,500	38,766
Cash and cash equivalents at beginning of the period	13,248	1,528
Cash and cash equivalents at end of the period	\$ 14,748	\$ 40,294

See accompanying notes to unaudited condensed consolidated financial statements.

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Athersys, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

1. Background

We are a biopharmaceutical company engaged in the development and commercialization of therapeutic products in one business segment. Our operations consist primarily of research and product development activities.

On May 24, 2007, BTHC VI, Inc. (BTHC VI) and its wholly owned subsidiary, B-VI Acquisition Corp., entered into an Agreement and Plan of Merger with Athersys, Inc. (Old Athersys). Pursuant to the terms of the Agreement and Plan of Merger, B-VI Acquisition Corp., which BTHC VI recently had incorporated for the purpose of completing the merger transaction described herein, merged with and into Old Athersys on June 8, 2007, with Old Athersys continuing as the surviving entity in the merger (the Merger). BTHC VI was a shell corporation with substantially no assets, liabilities or operations as of the date of the Merger, and had 299,622 shares of common stock outstanding. As a result of the Merger, Old Athersys became our wholly-owned subsidiary, and the business of Old Athersys became our sole operations. On August 31, 2007, Old Athersys changed its name to ABT Holding Company and BTHC VI changed its name to Athersys, Inc. Unless otherwise indicated, all references in this quarterly report to the Company or Athersys are (a) prior to the Merger, to ABT Holding Company (i.e., Old Athersys) and its subsidiaries and (b) following the Merger, to Athersys, Inc. and its subsidiaries, including ABT Holding Company.

BTHC VI's acquisition of Old Athersys on June 8, 2007 effected a change in control and was accounted for as a reverse acquisition whereby Old Athersys is the accounting acquirer for financial statement purposes. Accordingly, the financial statements of the Company presented reflect the historical results of Old Athersys and do not include the historical financial results of BTHC VI prior to the consummation of the Merger. The Company's authorized and issued shares of common and preferred stock have been retroactively restated for all historical periods presented to reflect the Merger exchange rate of 0.0358493. Basic and diluted net loss per share attributable to common stockholders have been computed using the retroactively restated common stock.

Immediately after the Merger, we completed an offering of 13,000,000 shares of common stock for aggregate gross proceeds of \$65.0 million in June 2007, which included the issuance of warrants to purchase 3,250,000 shares of common stock to the investors with an exercise price of \$6.00 and a five-year term. We also issued warrants to purchase 500,000 shares of common stock to the lead investor and warrants to purchase 1,093,525 shares of common stock to the placement agents, each with an exercise price of \$6.00 and a five-year term.

2. 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, 2007. The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair presentation of financial position and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

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

3. New Accounting Standards

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Accounting Standards (SFAS) No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements. The FASB delayed the effective date of SFAS No. 157 for non-financial assets and liabilities to fiscal years beginning after November 15, 2008. We adopted the provisions of SFAS No. 157 related to our financial assets and liabilities on January 1, 2008. See Note 6.

In May 2008, the FASB issued FASB Staff Position APB 14-1 (FSP 14-1), *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. FSP 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash on conversion to separately account for the liability and equity components in a manner that reflects the issuer's nonconvertible debt borrowing rate. The effective date of FSP 14-1 is January 1, 2009 for calendar year companies with retrospective application required for all periods presented for instruments that were outstanding during any period presented in the annual financial statements. We currently have no convertible debt instruments, but are evaluating the retrospective effect that FSP 14-1 will have on our financial statements.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*. This statement, which addresses the accounting for business acquisitions, is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited, and generally applies to business acquisitions completed after December 31, 2008. Among other things, the new standard requires that all acquisition-related costs be expensed as incurred, and that all restructuring costs related to acquired operations be expensed as incurred. This new standard also addresses the current and subsequent accounting for assets and liabilities arising from contingencies acquired or assumed and, for acquisitions both prior and subsequent to December 31, 2008, requires the acquirer to recognize changes in the amount of its deferred tax benefits that are recognizable because of a business combination either in income from continuing operations in the period of the combination or directly in contributed capital, depending on the circumstances. We do not expect its adoption to have a material impact on our financial statements.

In October 2008, the FASB issued FASB Staff Position (FSP), FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, which clarifies the application of SFAS No. 157, *Fair Value Measurements*, in a market that is not active and illustrates key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP did not have an impact on our financial statements.

4. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders are presented in conformity with SFAS No. 128, *Earnings per Share*, for all periods presented. In accordance with SFAS No. 128, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period.

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We have outstanding options and warrants, and prior to June 8, 2007, also had outstanding convertible debt and convertible preferred stock, which have not been used in the calculation of diluted net loss per share because to do so would be anti-dilutive. The following instruments were excluded from the calculation of diluted net loss per share attributable to common stockholders because their effects would be anti-dilutive:

- 1) Outstanding stock options to purchase 3,733,240 shares of common stock at September 30, 2008 for both the three-month and nine-month periods ended September 30, 2008, and 3,701,634 shares of common stock at September 30, 2007 for both the three-month and nine-month periods ended September 30, 2007;
- 2) Warrants to purchase 5,125,496 shares of common stock at September 30, 2008 and 2007 for each of the three-month and nine-month periods ended September 30, 2008 and September 30, 2007, respectively;
- 3) Shares of common stock issuable upon the conversion of convertible preferred stock in the amount of 213,388 during the nine-month period ended September 30, 2007; and
- 4) Shares of common stock issuable upon the conversion of convertible promissory notes in the approximate amount of 149,465 during the nine-month period ended September 30, 2007.

5. Comprehensive Loss

In accordance with SFAS No. 130, *Reporting Comprehensive Income*, all components of comprehensive income (loss), including net loss, are reported in the financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources.

Below is a reconciliation of net loss to comprehensive loss for all periods presented, in thousands.

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Net loss	\$ (4,493)	\$ (4,439)	\$ (13,279)	\$ (14,228)
Unrealized loss on available-for-sale securities	(45)		(105)	
Comprehensive loss	\$ (4,538)	\$ (4,439)	\$ (13,384)	\$ (14,228)

6. Fair Value of Financial Instruments

On January 1, 2008, we adopted SFAS No. 157 related to our financial assets and liabilities and the methods to measure fair value of assets and liabilities as set forth therein. Our available-for-sale securities typically include U.S. government obligations, corporate debt securities, floating rate notes and commercial paper. As of September 30, 2008, approximately 79% of our investments were in U.S. treasury bills.

SFAS No. 157 classifies the inputs used to measure fair value into the following hierarchy:

- Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 Unadjusted quoted prices in active markets for similar assets or liabilities, or unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are observable for the asset or liability.
- Level 3 Unobservable inputs for the asset or liability.

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The following table provides a summary of the fair values of our assets and liabilities under SFAS No. 157 (in thousands):

Description	Balance as of September 30, 2008	Fair Value Measurements at September 30, 2008 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

Available-for-sale securities	\$ 19,968	\$ 19,968	\$	\$
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Fair value is based upon quoted market prices in active markets. We had no level 2 or level 3 assets at September 30, 2008. We review and reassess the fair value hierarchy classifications on a quarterly basis. Changes from one quarter to the next related to the observability of inputs to a fair value measurement may result in a reclassification between hierarchy levels.

7. Stock-Based Compensation

In 2007, we adopted two equity incentive plans that authorized an aggregate of 4,500,000 shares of common stock for awards to employees, directors and consultants. These plans authorize the issuance of equity-based compensation in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units, and other stock-based awards to qualified employees, directors and consultants.

As of September 30, 2008, a total of 771,000 shares are available for issuance under our equity compensation plans and 3,729,000 options to purchase shares of common stock were outstanding. Also, options to purchase 4,240 shares of common stock are outstanding related to our old option plans prior to the Merger in June 2007. For the three-month period ended September 30, 2008, stock compensation expense was approximately \$501,000. During the three-month period ended September 30, 2008, we issued options to purchase an aggregate of 18,000 shares of common stock to an employee and a director. At September 30, 2008, total unrecognized estimated compensation cost related to unvested stock options was approximately \$3.6 million, which is expected to be recognized by September 30, 2012 using the straight-line method.

8. Long-Term Debt

A summary of our long-term debt outstanding is as follows (in thousands):

	September 30, 2008	December 31, 2007
Notes payable to lenders	\$	\$ 1,800
Discount related to warrant issuance		(16)
Total, net		1,784
Less current portion		1,784
	\$	\$

In November 2004, we issued \$7.5 million of notes payable to lenders, the proceeds of which were unrestricted and used for general corporate purposes. The notes were payable in 30 monthly payments after the initial interest-only period that expired December 1, 2005, with a fixed interest rate of 13% and a maturity date of June 1, 2008. The notes

were repaid in full in June 2008.

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The lenders retain a right to receive a milestone payment of \$2.25 million upon the occurrence of certain events as follows: (1) the entire amount upon (a) the merger with or into another entity where our stockholders do not hold at least a majority of the voting power of the surviving entity, (b) the sale of all or substantially all of our assets, or (c) our liquidation or dissolution; or (2) a portion of the amount from proceeds of equity financings not tied to specific research and development activities that are part of a research or development collaboration, in which case, the senior lenders will receive an amount equal to 10% of proceeds above \$5.0 million in cumulative gross proceeds until the milestone amount is paid in full. The milestone payment is payable in cash, except that if the milestone event is (2) above, we may elect to pay 75% of the milestone in shares of common stock at the per-share offering price. No amounts have been recorded in relation to the milestone as of September 30, 2008.

Upon the closing of our equity offering in June 2007, warrants to purchase 149,026 shares of common stock with an exercise price of \$5.00 per share and a seven-year term were issued to our lenders in accordance with the loan agreement. The value of the warrants was \$492,000 based on the Black-Scholes valuation of the underlying security, which was recognized as a debt discount over the remaining term of the loan.

9. Convertible Notes

Upon the closing of our equity offering in June 2007, convertible promissory notes issued to Angiotech Pharmaceuticals, Inc. pursuant to a collaboration, and to our bridge financing investors in 2006, were converted along with accrued interest into shares of common stock. The bridge notes, if not converted, were repayable with accrued interest at maturity, plus a repayment fee of 200% of the outstanding principal. We computed a premium on the debt in the amount of \$5.25 million due upon redemption, which was being accreted over the term of the notes using the effective interest method. The unamortized premium was reversed and recorded in additional paid-in-capital when the notes were converted into common stock upon the closing of our equity offering in June 2007.

10. Warrants

As of September 30, 2008, we had the following outstanding warrants to purchase shares of common stock:

Number of underlying shares	Exercise Price	Expiration
4,976,470	\$ 6.00	June 8, 2012
149,026	\$ 5.00	June 8, 2014
5,125,496		

11. Income Taxes

We have net operating loss and research and development tax credit carryforwards that may be used to reduce future taxable income and tax liabilities. However, as a result of the change in ownership related to our capital restructuring and equity offering in June 2007, we lost the use of a significant portion of our pre-Merger net operating loss carryforwards under Section 382 of the Internal Revenue Code. Our deferred tax assets have been fully offset by a valuation allowance due to our cumulative losses.

Table of Contents**12. Contingency**

We initially filed a shelf registration statement with the SEC in July 2007 covering the resale of 18,508,251 shares of common stock, which includes all shares of common stock issued in our equity offering in June 2007 and shares of common stock issuable upon exercise of warrants issued in the offering (as well as the 531,781 shares of common stock issued to the bridge noteholders and the 132,945 shares underlying their warrants). The registration statement was declared effective by the SEC on October 18, 2007. Under the registration rights agreement entered into in connection with our June 2007 equity offering, subject to certain exceptions, if the registration statement ceases to remain effective, a 1% cash penalty will be assessed for each 30-day period until the registration statement becomes effective again, capped at 10%. Because the penalty is based on the number of unregistered shares of common stock held by the investors in our June 2007 equity offering, our maximum penalty exposure will decline over time as investors sell their shares of common stock that were included in the registration statement.

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 financial statements and notes thereto included in this Quarterly Report on Form 10-Q and the audited financial statement and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2007. Operating results are not necessarily indicative of results that may occur in future periods.

Overview and Recent Developments

We are a biopharmaceutical company engaged in the discovery and development of therapeutic product candidates designed to extend and enhance the quality of human life. Through the application of our proprietary technologies and core capabilities, we have developed a pipeline of therapeutic product development programs in multiple diseases and conditions. We have established drug development programs in the areas of obesity and central nervous system disorders. In addition, applying our proprietary cell therapy platform, MultiStem[®], we have established therapeutic product development programs in the areas of cardiovascular disease and hematopoietic stem cell transplant support, as well as other areas.

5HT_{2c} Agonist Program – ATHX-105

We have an active development program focused on small molecules that stimulate the 5HT_{2c} receptor, a key receptor in the brain that regulates appetite and food intake. We have identified multiple compounds with the potential for treating obesity, and our lead candidate, ATHX-105, has been in clinical development. In January 2008, we completed a Phase I clinical trial in the United Kingdom with ATHX-105, the primary objective of which was to assess the short-term safety of ATHX-105 and to establish an appropriate dose range for subsequent clinical studies conducted in order to assess safety and effectiveness. There were no severe or serious adverse events observed in the clinical trial, no negative effects on cardiovascular, hematology or other clinical parameters, and no discontinuations due to adverse events. In the third quarter of 2008, we completed two additional Phase I studies in the United Kingdom that provided further safety and tolerability data for ATHX-105. These studies indicated that the drug is well absorbed throughout the gastrointestinal tract, demonstrating the potential for the development of a controlled release formulation.

In the third quarter of 2008, we filed an additional investigational new drug application, or IND, in the United States to initiate a Phase II clinical trial to examine the safety and effectiveness of ATHX-105 in clinically obese patients. We received a letter from the FDA in September 2008 with comments on the IND filing along with a request for additional information, placing the program on partial clinical hold.

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In response to this letter, we assembled relevant information and conducted certain non-clinical studies as requested by the FDA. We recently submitted this information and preliminary data from these studies to the FDA for its review and comment prior to submission of a formal response to the FDA's letter. We have discussed this information with the FDA, and based on these discussions, we believe that continued successful development of ATHX-105 may be difficult or impractical, even if our responses to the FDA comments and the requested additional information are ultimately adequate to support removal of the partial clinical hold. Furthermore, if the FDA authorizes ATHX-105 development to move forward, we believe that the increased risks of development could make it substantially more difficult or impractical for us to establish an attractive, third-party collaboration for the further development and commercialization of ATHX-105. We are continuing to work with outside experts to further evaluate recently obtained data, information and guidance from the FDA, as well as conduct some additional analysis. We intend to submit our formal response to the FDA in the fourth quarter of 2008 and hope to get feedback from the FDA by year-end to determine if further development would be possible and warranted. We believe that the FDA may request additional information and/or studies as a condition to lifting the partial clinical hold and, if so, we will evaluate the costs and benefits of conducting such studies in light of these changes to the development profile for ATHX-105. Based on the FDA response, and our assessment of available information, we may decide to amend, delay, suspend, or terminate the further development of this program.

MultiStem

We are developing MultiStem for multiple disease indications, and believe it could have therapeutic relevance across a range of areas. In the fourth quarter of 2007, we received FDA authorization to advance two MultiStem product development programs into clinical trials, in the areas of transplant support in leukemia and lymphoma patients and for treatment of damage from myocardial infarction. The application of MultiStem for certain cardiovascular applications, including myocardial infarction, is being developed with our partner, Angiotech Pharmaceuticals, Inc. ("Angiotech"). We initiated both of these trials in 2008 and have begun enrolling patients in each study. In addition to these programs, we are also developing MultiStem for certain other conditions and intend to seek FDA authorization to conduct clinical trials for some of these indications, including ischemic stroke.

In September 2008, Angiotech announced certain reorganization initiatives to reduce its costs, citing the potential need for an amendment and reduction in cash outlays related to our collaboration, on a list of possible actions. At this time, no such amendment or reduction has been requested or made to our collaboration, and Angiotech continues to fund its share of Phase I costs on a timely basis. In the event that Angiotech fails to fund its obligations under the terms of our contract, our net costs for the Phase I clinical study would increase or the study may be curtailed.

Other Programs

We are also developing pharmaceutical products for the treatment of certain conditions affecting the central nervous system, such as ADHD, narcolepsy and other cognitive or attention disorders. We plan to complete certain preclinical studies in the fourth quarter of 2008, and if appropriate, select a clinical candidate for this program within the next several months upon the successful conclusion of current studies.

Financial

In June 2007, we completed a merger with BTHC VI, Inc. and its wholly-owned subsidiary that was formed for the purpose of completing the merger. BTHC VI was a public shell corporation with substantially no assets, liabilities or operations. We continued as the surviving entity in the merger and our business became the sole operations of BTHC VI after the merger. BTHC VI's acquisition of us effected a change in control and was accounted for as a reverse acquisition whereby we were the accounting acquirer for financial statement purposes. Accordingly, our financial statements present our historical results and do not include the historical financial results of BTHC VI prior to the merger.

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Immediately after the merger, we completed an offering of 13,000,000 shares of common stock for aggregate gross proceeds of \$65.0 million in June 2007, which included the issuance of warrants to purchase 3,250,000 shares of common stock to the investors. We also issued warrants to purchase 500,000 shares of common stock to the lead investor and warrants to purchase 1,093,525 shares of common stock to the placement agents.

We have incurred losses since inception of operations in December 1995 and had an accumulated deficit of \$174 million at September 30, 2008. Our losses have resulted principally from costs incurred in research and development, clinical and preclinical product development, acquisition and licensing costs, and general and administrative costs associated with our operations. We have used the financing proceeds from private equity and debt offerings and other sources of capital to develop our technologies, to discover and develop therapeutic product candidates and to acquire certain technologies and assets. We have also built drug development capabilities that have enabled us to advance product candidates into clinical trials. We have established strategic collaborations that have provided revenues and capabilities to help further advance our product candidates, and we have also built a substantial portfolio of intellectual property.

Results of Operations

Since our inception, our revenues have consisted of license fees from our collaborators and grant proceeds primarily from federal and state grants. We have derived no revenue on the sale of FDA-approved products to date. Research and development expenses consist primarily of costs associated with external clinical and preclinical study fees, manufacturing costs, salaries and related personnel costs, legal expenses resulting from intellectual property application processes, and laboratory supply and reagent costs. We expense research and development costs as they are incurred. We expect to continue to make significant investments in research and development to enhance our technologies, advance clinical trials of our product candidates, expand our regulatory affairs and product development capabilities, conduct preclinical studies of our products and manufacture our products. General and administrative expenses consist primarily of salaries and related personnel costs, professional fees and other corporate expenses. To date, we have financed our operations through private equity and debt financing and investments by strategic collaborators. We expect to continue to incur substantial losses through at least the next several years.

The following tables set forth our revenues and expenses for the periods indicated. The following tables are stated in thousands.

Revenues

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2008	2007	2008	2007
License fees	\$ 885	\$ 500	\$ 1,728	\$ 1,123
Grant revenue	393	360	1,118	1,339
	\$ 1,278	\$ 860	\$ 2,846	\$ 2,462

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Research and development expenses

<i>Type of expense</i>	Three months ended		Nine months ended	
	September 30,	September 30,	September 30,	September 30,
	2008	2007	2008	2007
Personnel costs	\$ 675	\$ 621	\$ 2,241	\$ 2,067
Research supplies	267	126	649	485