

Capstone Therapeutics Corp.
Form 10-Q
August 10, 2012

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 June 30, 2012
period ended

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: 0-21214

CAPSTONE THERAPEUTICS CORP.
(Exact name of registrant as specified in its charter)

Delaware 86-0585310
(State or other jurisdiction of incorporation or (IRS Employer Identification No.)
organization)

1275 W. Washington Street, Suite 101, Tempe, Arizona 85281
(Address of principal executive offices) (Zip Code)

(602) 286-5520
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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. x Yes o No

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

Edgar Filing: Capstone Therapeutics Corp. - Form 10-Q

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. Large accelerated filer Accelerated filer ____
Non-accelerated filer ____ (do not check if a smaller reporting company) Smaller reporting company X

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

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

40,885,411 shares of common stock outstanding as of July 31, 2012

CAPSTONE THERAPEUTICS CORP.
(A Development Stage Company)

INDEX

	Page No.
<u>Forward Looking Statements</u>	3
<u>Part I Financial Information</u>	
<u>Item 1. Financial Statements (Unaudited)</u>	
<u>Condensed Balance Sheets as of June 30, 2012 and December 31, 2011</u>	4
<u>Condensed Statements of Operations for the three months and six months ended June 30, 2012 and 2011</u>	5
<u>Condensed Statements of Cash Flows for six months ended June 30, 2012 and 2011</u>	6
<u>Notes to Condensed Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
<u>Item 4. Controls and Procedures</u>	17
<u>Part II Other Information</u>	
<u>Item 1. Legal Proceedings</u>	17
<u>Item 1A. Risk Factors</u>	17
<u>Item 6. Exhibits</u>	18

EXHIBIT 31.1

EXHIBIT 31.2

EXHIBIT 32

Forward Looking Statements

We may from time to time make written or oral forward-looking statements, including statements contained in our filings with the Securities and Exchange Commission and our reports to stockholders. The safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 protects companies from liability for their forward looking statements if they comply with the requirements of that Act. This Quarterly Report on Form 10-Q should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2011, and contains forward-looking statements made pursuant to that safe harbor. These forward-looking statements relate to future events or to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by the use of words such as “may,” “could,” “expect,” “intend,” “plan,” “seek,” “anticipate,” “believe,” “estimate,” “predict,” “continue,” or the negative of these terms or other comparable terminology. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond our control and which could materially affect actual results, levels of activity, performance or achievements. Factors that may cause actual results to differ materially from current expectations, which we describe in more detail in our Annual Report for the year ended December 31, 2011, include, but are not limited to:

- the impact of our recently adopted plan to preserve cash during ongoing partnering efforts, including the reduction from eighteen employees to two employees and additional steps taken towards winding down internal operations;
 - unfavorable results of our product candidate development efforts;
 - unfavorable results of our pre-clinical or clinical testing;
 - delays in obtaining, or failure to obtain FDA approvals;
 - increased regulation by the FDA and other agencies;
 - the introduction of competitive products;
 - impairment of license, patent or other proprietary rights;
 - failure to achieve market acceptance of our products;
 - the impact of present and future joint venture, collaborative or partnering agreements or the lack thereof;
 - failure to successfully implement our drug development strategy;
- failure to obtain additional funds required to complete clinical trials and supporting research and production efforts necessary to obtain FDA approval for our product candidates; and
- effect of the ongoing qui tam litigation on our stock price, liquidity, and our ability to execute corporate or other transactions, or our ability to continue operations.

If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary significantly from what we projected. The forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events and are subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, business strategy and liquidity. We assume no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PART I – Financial Information

Item 1. Financial Statements

CAPSTONE THERAPEUTICS CORP.
(A Development Stage Company)
CONDENSED BALANCE SHEETS
(in thousands, except share data)

	June 30, 2012 (unaudited)	December 31, 2011
ASSETS		
Current assets		
Cash and cash equivalents	\$ 12,824	\$ 13,778
Other current assets	200	758
Total current assets	13,024	14,536
Furniture and equipment, net	34	160
Total assets	\$ 13,058	\$ 14,696
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 81	\$ 77
Accrued compensation	7	13
Other accrued liabilities	5	29
Total current liabilities	93	119
Stockholders' Equity		
Common Stock \$.0005 par value; 100,000,000 shares authorized; 40,885,411 shares in 2012 and 40,775,411 shares in 2011 issued and outstanding	20	20
Additional paid-in capital	189,150	189,074
Accumulated deficit (\$148,443 at June 30, 2012 and \$146,755 at December 31, 2011, accumulated during development stage period)	(176,205)	(174,517)
Total stockholders' equity	12,965	14,577
Total liabilities and stockholders' equity	\$ 13,058	\$ 14,696

See notes to unaudited condensed financial statements

CAPSTONE THERAPEUTICS CORP.
(A Development Stage Company)
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,		As a Development Stage Company August 5, 2004 - June 30, 2012
	2012	2011	2012	2011	
OPERATING EXPENSES					
General and administrative	\$ 393	\$ 797	\$ 817	\$ 1,962	\$ 30,539
Research and development	403	1,376	959	3,458	101,008
Purchased in-process research and development	-	-	-	-	34,311
Other	-	-	-	-	(375)
Total operating expenses	796	2,173	1,776	5,420	165,483
Interest and other income, net	(84)	(4)	(88)	(14)	(13,846)
Loss from continuing operations before taxes	712	2,169	1,688	5,406	151,637
Income tax benefit	-	-	-	-	(1,355)
Loss from continuing operations	712	2,169	1,688	5,406	150,282
Discontinued operations - net gain on sale of the bone device business, net of taxes of \$267	-	-	-	-	(2,202)
NET LOSS	\$ 712	\$ 2,169	\$ 1,688	\$ 5,406	\$ 148,080
Per Share Information:					
Net loss, basic and diluted	\$ 0.02	\$ 0.05	\$ 0.04	\$ 0.13	
Basic and diluted shares outstanding	40,878	40,775	40,875	40,775	

See notes to unaudited condensed financial statements

CAPSTONE THERAPEUTICS CORP.
(A Development Stage Company)
CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Six months ended June 30,		As a Development Stage Company August 5, 2004 - June 30, 2012
	2012	2011	
OPERATING ACTIVITIES			
Net loss	\$(1,688)	\$(5,406)	\$ (148,080)
Non cash items:			
Deferred tax expense	-	-	770
Depreciation and amortization, net of gain on sale	(44)	63	3,898
Non-cash stock compensation	76	107	4,900
Gain on sale of bone device business	-	-	(2,298)
In-process research and development	-	-	34,311
Change in other operating items:			
Interest, income taxes and other current assets	558	473	1,508
Accounts payable	4	139	(890)
Accrued liabilities	(30)	(136)	(3,005)
Cash flows used in operating activities	(1,124)	(4,760)	(108,886)
INVESTING ACTIVITIES			
Expenditures for furniture and equipment, net	-	(19)	(1,044)
Proceeds from sale of assets	170	-	7,170
Cash paid for assets of AzERx/CBI	-	-	(4,058)
Cash paid for patent assignment rights	-	-	(650)
Purchases of investments	-	-	(282,538)
Maturities of investments	-	-	340,476
Cash flows (used in) provided by investing activities	170	(19)	59,356
FINANCING ACTIVITIES			
Net proceeds from stock option exercises	-	-	4,612
Net proceeds from sale of stock	-	-	3,376
Common stock purchases	-	-	(1,041)
Cash flows provided by financing activities			6,947
NET DECREASE IN CASH AND CASH EQUIVALENTS	(954)	(4,779)	(42,583)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	13,778	24,387	55,407
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$12,824	\$19,608	\$ 12,824

Supplemental Disclosure of Non-Cash Investing Activities -	AzERx and CBI
AzERx/CBI Acquisitions:	
Current assets acquired	\$ 29
Patents acquired	2,142
Liabilities acquired, and accrued acquisition costs	(457)
Original investment reversal	(750)
In-process research and development acquired	34,311
Common stock issued for acquisition	(31,217)

Cash paid for acquisition	\$ 4,058
---------------------------	----------

See notes to unaudited condensed financial statements

6

CAPSTONE THERAPEUTICS CORP.
(A Development Stage Company)
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
June 30, 2012

OVERVIEW OF BUSINESS

Description of the Business

Capstone Therapeutics Corp. is a biotechnology company committed to developing a pipeline of novel peptides and other molecules aimed at helping patients with under-served medical conditions. Previously, we were focused on the development and commercialization of two product platforms: AZX100 and Chrysalin (TP508).

On October 13, 2011, our Board of Directors adopted a plan to preserve cash during our ongoing partnering efforts and effected a reduction from eighteen to four employees.

On January 20, 2012, we announced additional steps we took to preserve cash and move towards winding down internal operations while we continue efforts to create shareholder value through a development partnership (of clinical or pre-clinical stage assets) or other strategic transactions. Those steps included:

- We ceased clinical development of AZX100, formerly our principal drug candidate, in dermal scarring. Certain pre-clinical, manufacturing and regulatory projects related to AZX100 that are either required from a statutory perspective or are under contract will continue to their completion.
- We ceased all activities related to the development of TP508, our other drug candidate, and returned the patent and other intellectual property we own related to TP508 to the original licensor, the University of Texas Medical Branch at Galveston, Texas. We no longer have any interest in or rights to TP508.

On August 3, 2012, we entered into a joint venture (the “JV”) to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

The JV intends to implement an initial development plan to file an IND and pursue FDA approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (as an Orphan Drug). The initial funded development plan will extend through Phase 1a and 1b/2a clinical trials over an expected twenty-seven month period with a biomarker endpoint test targeting reduction of LDL. The JV may also fund research or studies to investigate Apo E mimetic molecules, including AEM-28 and analogs, for treatment of acute coronary syndrome.

Description of Prior and Current Peptide Drug Candidates.

AZX100 is a novel synthetic 24-amino acid peptide and is believed to have smooth muscle relaxation and anti-fibrotic properties. AZX100 is currently being evaluated for medically and commercially significant applications, such as prevention of hypertrophic and keloid scarring and treatment of pulmonary and peridural fibrosis. We filed an IND for a dermal scarring indication in 2007 and completed Phase 1a and Phase 1b safety clinical trials in dermal scarring in 2008. We commenced Phase 2 clinical trials in dermal scarring following shoulder surgery and keloid scar revision in the first quarter of 2009. During 2010 we completed and reported results for our clinical trials in keloid scar revision and substantially completed our Phase 2 clinical trial in dermal scarring following shoulder surgery. We completed and reported our Phase 2 clinical trial in dermal scarring following shoulder surgery in 2011. We have an exclusive worldwide license to AZX100. In the first quarter of 2012 we ceased clinical development of AZX100, our

principal drug candidate, in dermal scarring. Certain pre-clinical, manufacturing and regulatory projects related to AZX100 that are either required from a statutory perspective or are under contract will continue to their completion. We are currently focused on development partnering or licensing opportunities for AZX100.

Chrysalin (TP508), a novel synthetic 23-amino acid peptide, is believed to produce angiogenic and other tissue repair effects in part by 1) activating or upregulating endothelial nitric oxide synthase (eNOS); 2) cytokine modulation resulting in an anti-inflammatory effect; 3) inhibiting apoptosis (programmed cell death); and 4) promoting angiogenesis and revascularization. It may have therapeutic value in diseases associated with endothelial dysfunction. We primarily investigated Chrysalin in two indications, fracture repair and diabetic foot ulcer healing. Effective January 17, 2012, we ceased all activities related to the development of Chrysalin. We returned the intellectual property related to TP508 to the University of Texas Medical Branch in March 2012 and we no longer have any interest in or rights to TP508.

Apo E Mimetic Peptide Molecule – AEM-28

Apolipoprotein E is a 299 amino acid protein that plays an important role in lipoprotein metabolism. AEM-28 is a 28 amino acid mimetic of Apo E that contains a domain that anchors into a lipoprotein surface while also providing the Apo E binding domain that is avidly removed by heparin sulfate receptors in the liver. AEM-28 replicates the function of Apo E, and due to its small size, extends that function to LDL, which does not normally bind to the Apo E receptors on the liver. As a result, when AEM-28 is injected into the plasma, it associates with Apo B containing lipoproteins to facilitate their clearance into the liver by receptors specific for Apo E. Apo B lipoproteins (chylomicron remnants, VLDL, IDL and LDL) are proatherogenic and if elevated are associated with a significantly increased risk for cardiovascular disease. Since Apo B lipoproteins are the main substrates for the pathogenesis of atherosclerosis, lowering these lipoproteins is a major therapeutic strategy to prevent cardiovascular events. The Apo E receptor mediated uptake of AEM-28 enriched lipoproteins has enhanced capacity to remove the Apo B lipoproteins compared to the LDL/Apo B receptors in the liver and is the principal receptor mediated mechanism for the removal of post-prandial lipoproteins. By attaching to LDL, AEM-28 may provide an alternative pathway for clearance of these lipoproteins beyond the traditional LDL/Apo B receptor. AEM-28 as an Apo E mimetic has the potential to restore the ability of these atherogenic lipoproteins to be cleared from the plasma, completing the reverse cholesterol transport pathway, and thereby reducing cardiovascular risk. This is an important mechanism of action for AEM-28 that is not shared by other biological therapies presently in clinical development. For patients that lack LDL receptors (homozygous familial hypercholesterolemia, HoFH), AEM-28 may provide a therapeutic solution for this fatal orphan disease. This potential beneficial effect of AEM-28 provides an opportunity for rapid regulatory approval for an orphan indication. For patients that have a deficiency of LDL-receptors due to heterozygous familial hypercholesterolemia (HeFH), many of these patients cannot achieve adequate LDL-c goals on existing therapy. In summary, AEM-28 has a unique mechanism of action that may provide substantial reductions of all the atherogenic Apo B containing lipoproteins (VLDL, VLDL-R, IDL and LDL). This profile may provide a significant clinical advantage over other therapies nearing regulatory approval for HoFH such as mipomersen (anti-sense Apo B) or lomitapide (MTP inhibitor).

We remain a publicly-traded company, subject to the reporting requirements and other regulations of the Securities and Exchange Commission.

Company History

Prior to November 26, 2003, we developed, manufactured and marketed proprietary, technologically advanced orthopedic products designed to promote the healing of musculoskeletal bone and tissue, with particular emphasis on fracture healing and spine repair. Our product lines included bone growth stimulation and fracture fixation devices are referred to as our “Bone Device Business.”

On November 26, 2003, we sold our Bone Device Business. Our principal business remains focused on under-served medical conditions, although through biopharmaceutical approaches rather than through the use of medical devices.

On August 5, 2004, we purchased substantially all of the assets and intellectual property of Chrysalis Biotechnology, Inc. (“CBI”), including its exclusive worldwide license for Chrysalin for all medical indications. We became a development stage entity commensurate with the acquisition. Subsequently, our efforts were focused on research and development of Chrysalin with the goal of commercializing our product candidates.

On February 27, 2006, we purchased certain assets and assumed certain liabilities of AzERx, Inc. Under the terms of the transaction, we acquired an exclusive license for the core intellectual property relating to AZX100.

Our development activities for AZX100 and Chrysalin represented a single operating segment as they shared the same product development path and utilized the same Company resources. As a result, we determined that it is appropriate to reflect our operations as one reportable segment. Through June 30, 2012, we have incurred \$148 million in net losses as a development stage company.

On August 3, 2012, we entered into a joint venture (see Note C to the financial statements included in this quarterly report) to develop Apo E mimetic peptide molecule AEM-28 and analogs.

OrthoLogic Corp. commenced doing business under the trade name of Capstone Therapeutics on October 1, 2008, and we formally changed our name from OrthoLogic Corp. to Capstone Therapeutics Corp. on May 21, 2010.

In these notes, references to “we”, “our”, the “Company”, “Capstone Therapeutics”, “Capstone”, and “OrthoLogic” refer to Capstone Therapeutics Corp. References to our Bone Device Business refer to our former business line of bone growth stimulation and fracture fixation devices, including the OL1000 product line, SpinaLogic®, OrthoFrame® and OrthoFrame/Mayo.

Financial Statement Presentation

In the opinion of management, the unaudited condensed interim financial statements include all adjustments necessary for the fair presentation of our financial position, results of operations, and cash flows, and all adjustments were of a normal recurring nature. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the complete fiscal year.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to Securities and Exchange Commission rules and regulations, although we believe that the disclosures herein are adequate to make the information presented not misleading. These unaudited condensed financial statements should be read in conjunction with the financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2011. Information presented as of December 31, 2011 is derived from audited financial statements.

As discussed above, the Company has significantly curtailed its research and development operating activities for AZX100 and TP508. The Company has announced that it is in “wind down” mode, meaning that it is not currently planning to initiate any additional human clinical trials in dermal scar reduction with AZX100. Accordingly, the Company reduced its employee count from 18 in October 2011 to four as of December 31, 2011 and two as of June 30, 2012. The remaining employees have been focused on completing necessary regulatory and statutory requirements related to prior human clinical studies, as well as maintaining compliance with all applicable public company reporting requirements. The board of directors was also reduced from six to three members. Relating to future corporate strategy, the duration and timing of resolution of the qui tam lawsuit could affect our interest in or ability to: (a) engage in a strategic/merger transaction; (b) restart clinical operations based on a corporate partnering event or other shareholder support for renewing clinical studies; and (c) make a liquidating distribution to the shareholders. This uncertainty relating to corporate strategy resulted in substantial doubt about the Company’s ability to continue as a going concern. Effective with the formation of the joint venture to develop Apo E mimetic peptide molecule AEM-28 and analogs, on August 3, 2012, the uncertainty related to corporate strategy no longer exists. These financial statements do not include any adjustments that might result from the outcome of this uncertainty. The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company intends to continue to operate under the reduced workforce model but will actively participate in the development of AEM-28 and analogs through the newly formed joint venture.

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, and expenses in our financial statements and accompanying notes. Management bases its estimates on historical experience and various other assumptions believed to be reasonable. Although these estimates are based on management’s assumptions regarding current events and actions that may impact us in the future, actual results may differ from these estimates and assumptions.

Legal and Other Contingencies

As discussed in Part II, Item 1 of this Form 10-Q under the heading “Legal Proceedings” and in Note B, “Contingency – Legal Proceedings” in Notes to Financial Statements, the Company is subject to legal proceedings and claims that arise in the course of business. The Company records a liability when it is probable that a loss has been incurred and the amount is reasonably estimable. There is significant judgment required in both the probability determination and as to whether an exposure can be reasonably estimated. In the opinion of management, there was not at least a reasonable possibility the Company may have incurred a material loss with respect to loss contingencies. However, the outcome of legal proceedings and claims brought against the Company are subject to significant uncertainty. Therefore, if the qui tam legal matter is resolved against the Company in excess of management’s expectations, the Company’s financial statements could be materially adversely affected.

Loss per Common Share

In determining loss per common share for a period, we use weighted average shares outstanding during the period for primary shares and we utilize the treasury stock method to calculate the weighted average shares outstanding during the period for diluted shares. Utilizing the treasury stock method for the three and six month periods ended June 30, 2012, no shares of common stock were determined to be outstanding during the period and excluded from the calculations of diluted loss per share because they would be anti-dilutive. At June 30, 2012, options and warrants to purchase 3,373,597 shares of our common stock, at exercise prices ranging from \$0.17 to \$7.83 per share, were outstanding.

A. CASH AND CASH EQUIVALENTS

At June 30, 2012 and December 31, 2011, cash and cash equivalents included money market accounts and commercial paper with original maturities of less than 90 days.

B. CONTINGENCY – LEGAL PROCEEDINGS

In April 2009, we became aware of a qui tam complaint that was filed under seal by Jeffrey J. Bierman as Relator/Plaintiff on March 28, 2005 in the United States District Court for the District of Massachusetts against OrthoLogic and other companies that allegedly manufactured bone growth stimulation devices, including Orthofix International N.V., Orthofix, Inc., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. By order entered on March 24, 2009, the court unsealed the amended complaint. The amended complaint alleges various causes of action under the federal False Claims Act and state and city false claims acts premised on the contention that the defendants improperly promoted the sale, as opposed to the rental, of bone growth stimulation devices. The amended complaint also includes claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-kickback Act by providing free products to physicians, waiving patients' insurance co-payments, and providing inducements to independent sales agents to generate business. The Relator/Plaintiff is seeking civil penalties under various state and federal laws, as well as treble damages, which, in the aggregate could exceed the financial resources of the Company.

The United States Government declined to intervene or participate in the case. On September 4, 2009, the Relator/Plaintiff served the amended complaint on the Company. We sold our bone growth stimulation business in November 2003 and have had no further activity in the bone growth stimulation business since that date. We intend, in conjunction with the other defendants, to defend this matter vigorously and believe that at all times our billing practices in our bone growth stimulation business complied with applicable laws. On December 4, 2009, the Company, in conjunction with the other defendants, moved to dismiss the amended complaint with prejudice. In response to that motion, Relator/Plaintiff filed a second amended complaint. On August 17, 2010, the Company, in conjunction with the other defendants, moved to dismiss the second amended complaint with prejudice. That motion was denied by the court on December 8, 2010. On January 28, 2011, we, in conjunction with the other defendants, filed our answer to the second amended complaint. No trial date has been set. Discovery in the case has not yet begun.

Based upon the currently available information, we believe that the ultimate resolution of this matter will not have a material effect on our financial position, liquidity or results of operations. However, because of many questions of law and facts that may arise, the outcome of this litigation is uncertain. If we are unable to successfully defend or otherwise dispose of this litigation, and the Relator/Plaintiff is awarded the damages sought, the litigation would have a material adverse effect on our financial position, liquidity and results of operations and we would not be able to continue our business as it is presently conducted.

C. SUBSEQUENT EVENT – JOINT VENTURE FOR DEVELOPMENT OF APO E MIMETIC PEPTIDE MOLECULE AEM-28 AND ANALOGS

On August 3, 2012, we entered into a Contribution Agreement with LipimetiX LLC to form a joint venture, LipimetiX Development LLC (“JV”), to develop Apo E mimetic molecules, including AEM-28 and analogs. The Company will contribute \$6 million, which includes \$1 million for 600,000 voting common ownership units representing 60% ownership in JV, and \$5 million for 5,000,000 non-voting preferred ownership units, which have preferential distribution rights. The Contribution Agreement calls for initial funding of approximately \$3.3 million and funding of the remaining approximately \$2.7 million (held in escrow) upon milestone achievement of IND allowance by the FDA.

LipimetiX LLC will contribute to JV all intellectual property rights for Apo E mimetic molecules it owns and will assign its Exclusive License Agreement between the University of Alabama Birmingham Research Foundation (“UAB”) and LipimetiX LLC, for the UAB intellectual property related to Apo E mimetic molecules AEM-28 and analogs, in return for 400,000 common ownership units representing 40% ownership in JV and \$370,000 in cash (for certain initial patent related costs and legal expenses).

LipimetiX LLC was formed by the principals of Benu BioPharma, Inc. (“Benu”) and UAB to commercialize UAB’s intellectual property related to Apo E mimetic molecules, including AEM-28 and analogs. Benu is composed of Dennis Goldberg, Ph.D., Phillip M. Friden, Ph.D. and Eric M. Morrel, Ph.D. The Exclusive License Agreement calls for a 3% royalty payment to UAB on Net Product Sales by the JV and includes other terms consistent with institutional intellectual property license agreements.

Concurrent with entering into the Contribution Agreement and the First Amendment and Consent to Assignment of Exclusive License Agreement between LipimetiX LLC, UAB and the Company, the Company and LipimetiX LLC entered into a Limited Liability Company Agreement for JV which establishes a Joint Development Committee (“JDC”) to manage JV development activities. The JDC is composed of three members appointed by LipimetiX LLC and two members appointed by the Company. Non-development JV decisions, including the issuance of new equity, incurrence of debt, entry into strategic transactions, licenses or development agreements, sales of assets and liquidation, will be decided by a majority vote of the common ownership units.

The JV, on August 3, 2012, entered into a Management Agreement with Benu to manage JV development activities for a monthly fee of approximately \$63,000 and an Accounting Services Agreement with the Company to manage JV accounting and administrative functions for a monthly fee of \$10,000.

The financial position and results of operations of the joint venture will be presented on a consolidated basis with the financial position and results of operations of the Company. The Company has no obligation to contribute additional funds to JV or to assume any JV liabilities or to provide a guarantee of either JV performance or any JV liability.

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

The following is management’s discussion of significant events in the three and six month periods ended June 30, 2012 and factors that affected our interim financial condition and results of operations. This should be read in conjunction with our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors” included in our Annual Report on Form 10-K for the year ended December 31, 2011.

Overview of the Business

Capstone is a biotechnology company committed to developing a pipeline of novel peptides and other molecules aimed at helping patients with under-served conditions. Previously, we were focused on the development and commercialization of two product platforms: AZX100 and Chrysalin (TP508).

On October 13, 2011, our Board of Directors adopted a plan to preserve cash during our ongoing partnering efforts and effected a reduction from eighteen to four employees.

On January 20, 2012, we announced additional steps we have taken to preserve cash and move towards winding down operations while we continue efforts to create shareholder value through a development partnership (of clinical or pre-clinical stage assets) or other strategic transactions.

On August 3, 2012, we entered into a joint venture ("JV") to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

The JV intends to implement an initial development plan to file an IND and pursue FDA approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (as an Orphan Drug). The initial funded development plan will extend through Phase 1a and 1b/2a clinical trials over an expected twenty-seven month period with a biomarker endpoint test targeting reduction of LDL. The JV may also fund research or studies to investigate Apo E mimetic molecules, including AEM-28 and analogs, for treatment of acute coronary syndrome.

Description of Prior and Current Peptide Drug Candidates

AZX100 is a novel synthetic 24-amino acid peptide and is believed to have smooth muscle relaxation and anti-fibrotic properties. AZX100 is currently being evaluated for medically and commercially significant applications, such as prevention of hypertrophic and keloid scarring and treatment of pulmonary and peridural fibrosis. We filed an IND for a dermal scarring indication in 2007 and completed Phase 1a and Phase 1b safety clinical trials in dermal scarring in 2008. We commenced Phase 2 clinical trials in dermal scarring following shoulder surgery and keloid scar revision in the first quarter of 2009. During 2010 we completed and reported results for our clinical trials in keloid scar revision and substantially completed our Phase 2 clinical trial in dermal scarring following shoulder surgery. We completed and reported our Phase 2 clinical trial in dermal scarring following shoulder surgery in 2011. We have an exclusive worldwide license to AZX100. In the first quarter of 2012 we ceased clinical development of AZX100, our principal drug candidate, in dermal scarring. Certain pre-clinical, manufacturing and regulatory projects related to AZX100 that are either required from a statutory perspective or are under contract will continue to their completion. We are currently focused on development partnering or licensing opportunities for AZX100.

Chrysalin (TP508), a novel synthetic 23-amino acid peptide, is believed to produce angiogenic and other tissue repair effects in part by 1) activating or upregulating endothelial nitric oxide synthase (eNOS); 2) cytokine modulation resulting in an anti-inflammatory effect; 3) inhibiting apoptosis (programmed cell death); and 4) promoting angiogenesis and revascularization. It may have therapeutic value in diseases associated with endothelial dysfunction. We primarily investigated Chrysalin in two indications, fracture repair and diabetic foot ulcer healing. Effective January 17, 2012, we ceased all activities related to the development of Chrysalin. We returned the intellectual property related to TP508 to the University of Texas Medical Branch in March 2012 and we no longer have any interest in or rights to TP508.

Apo E Mimetic Molecule – AEM-28

Apolipoprotein E is a 299 amino acid protein that plays an important role in lipoprotein metabolism. AEM-28 is a 28 amino acid mimetic of Apo E that contains a domain that anchors into a lipoprotein surface while also providing the Apo E binding domain that is avidly removed by heparin sulfate receptors in the liver. AEM-28 replicates the function of Apo E, and due to its small size, extends that function to LDL, which does not normally bind to the Apo E receptors on the liver. As a result, when AEM-28 is injected into the plasma, it associates with Apo B containing lipoproteins to facilitate their clearance into the liver by receptors specific for Apo E. Apo B lipoproteins (chylomicron remnants, VLDL, IDL and LDL) are proatherogenic and if elevated are associated with a significantly increased risk for cardiovascular disease. Since Apo B lipoproteins are the main substrates for the pathogenesis of atherosclerosis, lowering these lipoproteins is a major therapeutic strategy to prevent cardiovascular events. The Apo E receptor mediated uptake of AEM-28 enriched lipoproteins has enhanced capacity to remove the Apo B lipoproteins compared to the LDL/Apo B receptors in the liver and is the principal receptor mediated mechanism for the removal of post-prandial lipoproteins. By attaching to LDL, AEM-28 may provide an alternative pathway for clearance of these lipoproteins beyond the traditional LDL/Apo B receptor. AEM-28 as an Apo E mimetic has the potential to restore the ability of these atherogenic lipoproteins to be cleared from the plasma, completing the reverse cholesterol transport pathway, and thereby reducing cardiovascular risk. This is an important mechanism of action for AEM-28 that is not shared by other biological therapies presently in clinical development. For patients that lack LDL receptors (homozygous familial hypercholesterolemia or HoFH), AEM-28 may provide a therapeutic solution. This potential beneficial effect of AEM-28 for patients suffering from HoFH, which is a fatal disease, provides an opportunity for rapid regulatory approval for an orphan indication. For patients that have a deficiency of LDL-receptors due to heterozygous familial hypercholesterolemia (HeFH), many of these patients cannot achieve adequate LDL-c goals on existing therapy. In summary, AEM-28 has a unique mechanism of action that may provide substantial reductions of all the atherogenic Apo B containing lipoproteins (VLDL, VLDL-R, IDL and LDL). This profile may provide a significant clinical advantage over other therapies nearing regulatory approval for HoFH such as mipomersen (anti-sense Apo B) or lomitapide (MTP inhibitor).

We remain a publicly-traded company, subject to the reporting requirements and other regulations of the Securities and Exchange Commission.

Critical Accounting Policies

Our critical accounting policies are those that affect, or could affect our financial statements materially and involve a significant level of judgment by management. The accounting policies and related risks described in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 21, 2012, for the year ended December 31, 2011 are those that depend most heavily on these judgments and estimates. As of June 30, 2012, there have been no material changes to any of the critical accounting policies contained in our Annual Report for the year ended December 31, 2011.

Results of Operations Comparing Three-Month Period Ended June 30, 2012 to the Corresponding Period in 2011.

General and Administrative (“G&A”) Expenses: G&A expenses related to our ongoing operations were \$393,000 in the second quarter of 2012 compared to \$797,000 in the second quarter of 2011. The decline in administration expenses between periods resulted from the reduction in staff in the fourth quarter of 2011 and other actions taken by the Company to wind down internal operations.

Research and Development Expenses: Research and development expenses were \$403,000 for the second quarter of 2012 compared to \$1,376,000 for the second quarter of 2011. Our research and development expenses decreased in the second quarter of 2012 compared to the same period in 2011 primarily due to the reduction in staff in the fourth quarter of 2011 and other actions taken by the Company to wind down internal operations.

Interest and Other Income, Net: Interest and other income, net increased from \$4,000 in the second quarter of 2011 to \$84,000 in the second quarter of 2012 due to the recognition of a \$80,000 gain on the sale of lab equipment in the second quarter of 2012.

Net Loss: We incurred a net loss in the second quarter of 2012 of \$0.7 million compared to a net loss of \$2.2 million in the second quarter of 2011. The decrease in the net loss for the second quarter of 2012 compared to the same period in 2011 resulted primarily from the reduction in staff in the fourth quarter of 2011 and other actions taken by the Company to wind down internal operations.

Results of Operations Comparing Six-Month Period Ended June 30, 2012 to the Corresponding Period in 2011.

General and Administrative (“G&A”) Expenses: G&A expenses related to our ongoing operations were \$817,000 in the first six months of 2012 compared to \$1,962,000 in the first six months of 2011. The decline in administration expenses between periods resulted from the reduction in staff in the fourth quarter of 2011 and other actions taken by the Company to wind down internal operations.

Research and Development Expenses: Research and development expenses were \$959,000 for the first six months of 2012 compared to \$3,458,000 for the first six months of 2011. Our research and development expenses decreased in the first six months of 2012 compared to the same period in 2011 primarily due to the reduction in staff in the fourth quarter of 2011 and other actions taken by the Company to wind down internal operations.

Interest and Other Income, Net: Interest and other income, net increased from \$14,000 in the first six months of 2011 to \$88,000 in the first six months of 2012 due to the recognition of a \$80,000 gain on the sale of lab equipment in the second quarter of 2012.

Net Loss: We incurred a net loss in the first six months of 2012 of \$1.7 million compared to a net loss of \$5.4 million in the first six months of 2011. The decrease in the net loss for the first six months of 2012 compared to the same period in 2011 resulted primarily from the reduction in staff in the fourth quarter of 2011 and other actions taken by the Company to wind down internal operations.

Liquidity and Capital Resources

We have historically financed our operations through operating cash flows and the public and private sales of equity securities. However, with the sale of our Bone Device Business in November 2003, we sold all of our revenue producing operations. Since that time, we have relied on our cash and investments to finance all our operations, the focus of which was research and development of our Chrysalin and AZX100 product candidates. We received approximately \$93.0 million in cash from the sale of our Bone Device Business. On December 1, 2005, we received the additional \$7.2 million, including interest, from the escrow balance related to the sale of the Bone Device Business. On February 27, 2006, we entered into an agreement with Quintiles (see Note 15 to our Annual Report on Form 10-K filed with the Securities Exchange Commission on March 5, 2008), which provided an investment by Quintiles in our common stock, of which \$2,000,000 was received on February 27, 2006 and \$1,500,000 was received on July 3, 2006. In 2010, we received a tax refund of \$1,009,000 from the tax year 2003, related to federal tax legislation recorded in the fourth quarter of 2009, and in 2010 we were awarded a Therapeutic Discovery Project federal grant of \$244,000, of which \$78,000 was received in 2010. In 2011, we received an Arizona State income tax refund for the 2010 tax year of \$181,000 and we received an additional Arizona State income tax refund of \$158,000

in 2012 for the 2011 tax year. We also received net proceeds of \$4,612,000 from the exercise of stock options during our development stage period and \$170,000 from the sale of lab equipment in the second quarter of 2012. At June 30, 2012, we had cash and cash equivalents of \$12.8 million.

On October 13, 2011, our Board of Directors adopted a plan to preserve cash during our ongoing partnering efforts and effected a reduction from 18 employees to four employees. The Company has attempted to retain the services of several former key employees through consulting agreements.

On January 20, 2012, we took additional actions to preserve cash and move towards winding down internal operations while we continued efforts to create shareholder value through a development partnership (of clinical or pre-clinical stage assets) or other strategic transactions. These additional actions included the following:

- We ceased clinical development of AZX100, formerly our principal drug candidate, in dermal scarring. Certain pre-clinical, manufacturing and regulatory projects related to AZX100 that are either required from a statutory perspective or are under contract will continue to their completion.
- We ceased all activities related to the development of TP508, our other drug candidate, and returned the patent and other intellectual property we own related to TP508 to the original licensor, the University of Texas Medical Branch at Galveston, Texas. We no longer have any interest in or rights to TP508.

On August 3, 2012, we entered into a joint venture (“JV”) to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

The JV intends to implement an initial development plan to file an IND and pursue FDA approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (as an Orphan Drug). The initial funded development plan will extend through Phase 1a and 1b/2a clinical trials over an expected twenty-seven month period with a biomarker endpoint test targeting reduction of LDL. The JV may also fund research or studies to investigate Apo E mimetic molecules, including AEM-28 and analogs, for treatment of acute coronary syndrome.

If we continue a plan to wind down internal operations in 2012, we currently estimate that we will expend in the range of \$2.5 million in 2012, excluding our contribution of \$6 million to LipimetiX Development LLC and litigation costs related to the qui tam action, which cannot be estimated at this time and could be significant. Currently our planned operations in 2012 consist of continuing our development partnering efforts for AZX100, investigating pre-clinical, clinical or other strategic options for AZX100, monitoring and participating in the management of LipimetiX Development LLC’s AEM-28 and analogs development activities, and maintaining the required level of corporate governance and reporting required to comply with Securities and Exchange Commission rules and regulations.

Our future research and development and other expenses will vary significantly from prior periods and depend on the Company’s decisions on its future AZX100 development plans, results of our efforts to create shareholder value with AZX100, LipimetiX Development LLC operations and qui tam litigation activity.

We anticipate that our cash and short-term investments at June 30, 2012 will be sufficient to meet our presently projected cash and working capital requirements for the next year. However, to complete the clinical trials and supporting research and production efforts necessary to obtain FDA approval for product candidates would require us to obtain substantial additional capital. New sources of funds, including raising capital through the sales of our debt or equity securities, joint venture or other forms of joint development arrangements, sales of development rights, or licensing agreements, may not be available or may only be available on terms that would have a material adverse impact on our existing stockholders’ interests. We cannot currently predict the amount of funds that will be required to bring the qui tam action to a final resolution.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial and accounting officer, has reviewed and evaluated our disclosure controls and procedures (as defined in the Securities Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 10-Q. Based on that evaluation, our management, including our principal executive officer and principal financial and accounting officer, has concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Form 10-Q in ensuring that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and is accumulated and communicated to management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II – Other Information

Item 1. Legal Proceedings

Reference is made to Item 3. Legal Proceedings in our Form 10-K filed with the Securities and Exchange Commission on March 21, 2012 and to Note B in this report, which information is incorporated in this Item 1 by reference.

Item 1A. Risk Factors

There are no material changes from the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011, except as follows:

The development of Apo E mimetic peptide molecule AEM-28 and analogs by LipimetiX Development LLC may not result in a liquidity event or a liquidity event, if one occurs, may be insufficient in size and our investment in LipimetiX Development LLC may not be recovered.

On August 3, 2012, we entered into a joint venture with LipimetiX LLC to develop the Apo E mimetic molecule AEM-28 and analogs and we agreed to contribute \$6 million to the joint venture. Our cash contribution to the joint venture represents a substantial proportion of our available cash.

The initial funded development plan will be focused on the development of treatments for Homozygous Familial Hyperlipidemia and Refractory Hypercholesterolemia, is dependent on receipt of Orphan Drug designation for Homozygous Familial Hypercholesterolemia by the FDA, and will extend through Phase 1a and 1b/2a clinical trials. There is no assurance that AEM-28 will receive Orphan Drug designation for Homozygous Familial Hyperlipidemia. If Orphan Drug designation is not received or if our planned pre-clinical studies or clinical trials do not yield favorable results, the joint venture development efforts will not be successful and we may not recover our investment. Even if our development efforts are successful, a liquidity event, if any, may be insufficient in size to recover our investment.

Item 6. Exhibits

See the Exhibit Index following this report.

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.

CAPSTONE THERAPEUTICS CORP.
(Registrant)

Signature	Title	Date
/s/ John M. Holliman, III John M. Holliman, III	Executive Chairman (Principal Executive Officer)	August 10, 2012
/s/ Les M. Taeger Les M. Taeger	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	August 10, 2012

Capstone Therapeutics Corp.
(the "Company")
Exhibit Index to Quarterly Report on Form 10-Q
For the Quarterly Period Ended June 30, 2012

Exhibit No.	Description	Incorporated by Reference To:	Filed Herewith
10.1	Contribution Agreement by and among LipimetiX, LLC, Capstone Therapeutics Corp., LipimetiX Development, LLC, The UAB Research Foundation, Dennis I. Goldberg, Ph.D. ("Goldberg"), Philip M. Friden, Ph.D., Eric Morrell, Ph.D., G. M. Anantharamaiah, Ph.D. and Palgunachari Mayakonda, Ph.D., Frederick Meyer, Ph.D., Michael Webb, and Jeffrey Elton, Ph.D., effective as of August 3, 2012.		X
10.2	Limited Liability Company Agreement of LipimetiX Development, LLC, by and among LipimetiX Development, LLC, Capstone Therapeutics Corp., and the other members and managers party thereto, effective as of August 3, 2012.		X
10.3	First Amendment and Consent to Assignment of Exclusive License Agreement by and among The UAB Research Foundation, LipimetiX, LLC and LipimetiX Development, LLC, dated as of August 3, 2012.		X
10.4	Management Agreement by and among LipimetiX Development, LLC, Benu BioPharma, Inc., Dennis I. Goldberg, Ph.D., Phillip M. Friden, Ph.D., and Eric M. Morrel, Ph.D., effective as of August 3, 2012.		X

Edgar Filing: Capstone Therapeutics Corp. - Form 10-Q

Exhibit No.	Description	Incorporated by Reference To:	Filed Herewith
10.5	Accounting Services Agreement by and among LipimetiX Development, LLC and Capstone Therapeutics Corp., effective as of August 3, 2012.		X
10.6	Escrow Agreement by and among Capstone Therapeutics Corp., LipimetiX Development, LLC dated as of August 3, 2012		X
10.7	Exclusive License Agreement between the UAB Research Foundation and LipimetiX LLC dated August 26, 2011		X
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as amended		X
31.2	Certification of Principal Financial and Accounting Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as amended		X
32	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350*		
101	The following financial information from our Quarterly Report on Form 10-Q for the second quarter of fiscal year 2012, filed with the SEC on August 10, 2012 formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Balance Sheets as of June 30, 2012 and December 31, 2011, (ii) the Condensed Statements of Operations for the three and six months ended June 30, 2012 and 2011 and the ninety five months ended June 30, 2012, (iii) the Condensed Statements of Cash Flows for the six months ended June 30, 2012 and 2011 and the ninety five months ended June 30, 2012, and (iv) Notes to Unaudited Condensed Financial Statements. *		

* Furnished herewith

