

Capstone Therapeutics Corp.  
Form 10-Q  
November 12, 2013

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, 2013

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  
(State or other jurisdiction of incorporation or organization)

86-0585310  
(IRS Employer Identification No.)

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  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 October 31, 2013

CAPSTONE THERAPEUTICS CORP.  
(A Development Stage Company)

INDEX

	Page No.
Forward Looking Statements	3
<b>Part I Financial Information</b>	
<b>Item 1. Financial Statements (Unaudited)</b>	
Condensed Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012	4
Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2013 and 2012	5
Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 and 2012	6
Notes to Condensed Consolidated Financial Statements	7
<b>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</b>	<b>8</b>
<b>Item 4. Controls and Procedures</b>	<b>16</b>
<b>Part II Other Information</b>	
<b>Item 1. Legal Proceedings</b>	<b>16</b>
<b>Item 1A. Risk Factors</b>	<b>16</b>
<b>Item 6. Exhibits</b>	<b>16</b>

EXHIBIT 10.1  
EXHIBIT 31.1  
EXHIBIT 31.2  
EXHIBIT 32  
EXHIBIT 101

## 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, 2012, 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 Form 10-K for the year ended December 31, 2012, include, but are not limited to:

- the impact of our actions to preserve cash, including the reduction from eighteen employees to two employees and additional steps taken towards a virtual operating model;
  - unfavorable results of product candidate development efforts;
  - unfavorable results of 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;
- the impact of present and future joint venture, collaborative or partnering agreements or the lack thereof;
  - failure to successfully implement our drug development strategy for AEM-28;
- failure to obtain additional funds required to complete clinical trials and supporting research and production efforts necessary to obtain FDA approval for 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 CONSOLIDATED BALANCE SHEETS  
(in thousands, except share data)

	September 30, 2013 (unaudited)	December 31, 2012
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents, \$2,514 reserved at September 30, 2013	\$ 7,183	\$ 10,205
Other current assets	83	383
Total current assets	7,266	10,588
Patent license rights, net	862	980
Furniture and equipment, net	5	23
Total assets	\$ 8,133	\$ 11,591
<b>LIABILITIES AND EQUITY</b>		
Current liabilities		
Accounts payable	\$ 200	\$ 233
Other accrued liabilities	6	61
Total current liabilities	206	294
Equity		
Capstone Therapeutics Corp. Stockholders' Equity		
Common Stock \$.0005 par value; 100,000,000 shares authorized; 40,885,411 shares in 2013 and 2012 issued and outstanding	20	20
Additional paid-in capital	189,210	189,181
Accumulated deficit (\$153,541 at September 30, 2013 and \$150,335 at December 31, 2012, accumulated during development stage period)	(181,303 )	(178,097 )
Total Capstone Therapeutics Corp. stockholders' equity	7,927	11,104
Noncontrolling interest	-	193
Total equity	7,927	11,297
Total liabilities and equity	\$ 8,133	\$ 11,591

See notes to unaudited condensed consolidated financial statements

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

	Three months ended September 30,		Nine months ended September 30,		As a Development Stage Company August 5, 2004 - September 30, 2013
	2013	2012	2013	2012	
<b>OPERATING EXPENSES</b>					
General and administrative	\$ 245	\$ 480	\$ 956	\$ 1,297	\$ 32,442
Research and development	958	667	2,619	1,626	105,053
Purchased in-process research and development	-	-	-	-	34,311
Other	-	-	-	-	(375 )
Total operating expenses	1,203	1,147	3,575	2,923	171,431
Interest and other income, net	(1 )	(5 )	(155 )	(93 )	(14,008 )
Loss from continuing operations before taxes	1,202	1,142	3,420	2,830	157,423
Income tax benefit	-	-	(21 )	-	(1,376 )
Loss from continuing operations	1,202	1,142	3,399	2,830	156,047
Discontinued operations - net gain on sale of the bone device business, net of taxes of \$267	-	-	-	-	(2,202 )
<b>NET LOSS</b>	<b>1,202</b>	<b>1,142</b>	<b>3,399</b>	<b>2,830</b>	<b>153,845</b>
Less: Net Loss attributable to the noncontrolling interest	-	(191 )	(193 )	(191 )	(667 )
Net Loss attributable to Capstone Therapeutics Corp. stockholders	\$ 1,202	\$ 951	\$ 3,206	\$ 2,639	\$ 153,178
<b>Per Share Information:</b>					
Net loss, basic and diluted, attributable to Capstone Therapeutic Corp. stockholders	\$ 0.03	\$ 0.02	\$ 0.08	\$ 0.06	
Basic and diluted shares outstanding	40,885	40,885	40,885	40,879	

See notes to unaudited condensed consolidated financial statements

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

	Nine months ended September 30,		As a Development Stage Company August 5, 2004 - September 30, 2013
	2013	2012	
<b>OPERATING ACTIVITIES</b>			
Net loss	\$(3,399 )	\$(2,830 )	\$ (153,845 )
Non cash items:			
Deferred tax expense	-	-	770
Depreciation and amortization, net of gain on sale	132	(14 )	4,103
Non-cash stock compensation	29	104	4,960
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	300	428	1,625
Accounts payable	(33 )	132	(771 )
Accrued liabilities	(55 )	(37 )	(3,010 )
Cash flows used in operating activities	(3,026 )	(2,217 )	(114,155 )
<b>INVESTING ACTIVITIES</b>			
Expenditures for furniture and equipment, net	-	-	(1,044 )
Proceeds from sale of assets	4	172	7,176
Cash paid for assets of AzERx/CBI	-	-	(4,058 )
Cash paid for patent rights	-	(378 )	(1,028 )
Purchases of investments	-	-	(282,538 )
Maturities of investments	-	-	340,476
Cash flows provided by (used in) investing activities	4	(206 )	58,984
<b>FINANCING ACTIVITIES</b>			
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
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(3,022 )</b>	<b>(2,423 )</b>	<b>(48,224 )</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>10,205</b>	<b>13,778</b>	<b>55,407</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$7,183</b>	<b>\$ 11,355</b>	<b>\$ 7,183</b>
<b>Supplemental Disclosure of Non-Cash Investing Activities -</b>			
	<b>LipimetiX</b>		<b>LipimetiX/AzERx/CBI</b>
<b>LipimetiX/AzERx/CBI Acquisitions:</b>			
Current assets acquired	\$ -		\$ 29
Patent rights acquired	1,045		3,187
Liabilities acquired, and accrued acquisition costs	-		(457 )
Original investment reversal	-		(750 )
In-process research and development acquired	-		34,311
Noncontrolling interest	(667 )		(667 )
Common stock issued for acquisition	-		(31,217 )

Cash paid	\$ 378	\$ 4,436
-----------	--------	----------

See notes to unaudited condensed consolidated financial statements

6

---



CAPSTONE THERAPEUTICS CORP.  
(A Development Stage Company)  
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
September 30, 2013

NOTE A. 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). We no longer have any interest in or rights to Chrysalin. On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, (the "JV") to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

In 2012 we wound down internal operations, ceased clinical development of AZX100 in dermal scarring, formerly our principal drug candidate, and moved to a more virtual operating model. Certain manufacturing and regulatory activities related to AZX100 that are required either from a statutory perspective or for reporting purposes, will continue. We are also performing limited pre-clinical studies with AZX100 in fibrosis. We are currently seeking development partnering or licensing opportunities for AZX100 in dermal scarring, pulmonary fibrosis and peridural fibrosis.

The JV intends to implement an initial development plan to file an IND (USA) and a CTA (Canada) and pursue FDA approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012). 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 cholesterol. 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. For a description of the JV, please refer to Note B below.

The Company intends to limit its internal operations in a virtual operating model while 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.

Description of Current Peptide Drug Candidates

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 removed by heparin sulfate receptors in the liver. 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. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia, HoFH), or have Severe Refractory Hypercholesterolemia, AEM-28 may provide a therapeutic solution. Our joint venture has an Exclusive License Agreement with the University of Alabama Birmingham Research Foundation for AEM-28 and certain of its analogs.



## AZX100

AZX100 is a novel synthetic 24-amino acid peptide and is believed to have smooth muscle relaxation and anti-fibrotic properties. AZX100 has been 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.

## 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, which 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. (In March 2012, we returned all rights to the Chrysalin intellectual property and no longer have any interest in, or rights to Chrysalin.)

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.

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, (see Note B below) to develop Apo E mimetic peptide molecule AEM-28 and analogs.

Our development activities represent 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 September 30, 2013, we have incurred \$153 million in net losses as a development stage company.

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”, “us”, 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. References to our joint venture refer to LipimetiX Development, LLC.

## 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. The financial statements include the consolidated results of Capstone Therapeutics Corp. and our 60% owned subsidiary, LipimetiX Development, LLC. Intercompany transactions have been eliminated.

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, 2012. Information presented as of December 31, 2012 is derived from audited financial statements.

## 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 C, "Contingency – Legal Proceedings" in Notes to Financial Statements, the Company is subject to legal proceedings and claims that arise in the ordinary 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.

## Joint Venture Accounting

The Company entered into a joint venture to which it has contributed \$6,000,000, and the noncontrolling interests have contributed certain patent license rights. Neither the Company nor the noncontrolling interests have an obligation to contribute additional funds to the joint venture or to assume any joint venture liabilities or to provide a guarantee of either joint venture performance or any joint venture liability. The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. Joint venture losses were recorded on the basis of common ownership equity interests (60% Company / 40% noncontrolling interests) until common ownership equity was reduced to \$0. Subsequent joint venture losses have been allocated to the preferred ownership equity (100% Company). Subsequent to March 31, 2013, all joint venture losses are being allocated to the Company.



## 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 nine month period ended September 30, 2013, 130,611 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 September 30, 2013, options and warrants to purchase 3,464,935 shares of our common stock, at exercise prices ranging from \$0.16 to \$7.83 per share, were outstanding.

## Cash and Cash Equivalents

At September 30, 2013, cash and cash equivalents included money market accounts. Cash and cash equivalents at September 30, 2013 include \$2.5 million held in, and reserved for use by, LipimetiX Development, LLC and unavailable for general use by the Company.

## Note B. 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 contributed \$6 million, which included \$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 called for initial funding of approximately \$3.3 million and placing the remaining \$2.7 million in escrow to be released upon milestone achievement of IND allowance by the FDA or mutual agreement of both parties. On August 23, 2013, \$800,000 was released from the escrow account and additional escrow funds may be released from the escrow account in 2013 and 2014.

LipimetiX LLC contributed to JV all intellectual property rights for Apo E mimetic molecules it owned and assigned its Exclusive License Agreement between the University of Alabama Birmingham Research Foundation (“UABRF”) and LipimetiX LLC, for the UABRF intellectual property related to Apo E mimetic molecules AEM-28 and analogs, in return for 400,000 voting common ownership units representing 40% ownership in JV, and \$378,000 in cash (for certain initial patent related costs and legal expenses).

LipimetiX LLC was formed by the principals of Benu BioPharma, Inc. (“Benu”) and UABRF to commercialize UABRF’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 payment of patent filing, maintenance and other related patent fees, as well as a royalty of 3% on Net Sales of Licensed Products during the Term of the Agreement. The Agreement terminates upon the expiration of all Valid Patent Claims within the Licensed Patents, which are currently estimated to expire between 2019 and 2033. The Agreement also calls for annual maintenance payments of \$25,000, various milestone payments of \$50,000 to \$1,000,000 and minimum royalty payments of \$1,000,000 to \$5,000,000 per year commencing on January 1 of the first calendar year following the year in which the First Commercial Sale occurs. UABRF will also receive 15% of Non Royalty Income received after August 25, 2014 and a greater percentage if received before that date.

Concurrent with entering into the Contribution Agreement and the First Amendment and Consent to Assignment of Exclusive License Agreement between LipimetiX LLC, UABRF 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 during the twenty-seven month development period, and an Accounting Services Agreement with the Company to manage JV accounting and administrative functions. The current accounting services fee is \$1,000 a month. The Management Agreement provides for an additional performance measured incentive fee of up to \$250,000.

The joint venture formation was as follows (\$000's):

Patent license rights	\$ 1,045
Noncontrolling interests	\$( 667 )
Cash paid at formation	\$378

Patent license rights were recorded at their estimated fair value and are being amortized on a straight-line basis over the key patent life of eighty months.

The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. The joint venture agreement requires profits and losses to be allocated on the basis of common ownership equity interests (60% Company / 40% noncontrolling interests). However, for the Company's consolidated financial statement, joint venture losses were recorded on the basis of common ownership equity interests (60% Company / 40% noncontrolling interests) until common ownership equity was reduced to \$0. Subsequent joint venture losses have been allocated to the preferred ownership equity (100% Company). Subsequent to March 31, 2013, all joint venture losses are being allocated to the Company.

The joint venture incurred operating expenses, prior to the elimination of intercompany transactions, of \$2,253,000, for the nine months ended September 30, 2013 and \$3,436,000 for the period from August 3, 2012 (inception) to September 30, 2013, of which \$2,059,000 and \$2,769,000, respectively, have been allocated to the Company. The joint venture operating expenses are included in research and development expenses in the condensed consolidated statements of operations.

Neither the Company nor the noncontrolling interests have an obligation to contribute additional funds to the joint venture or to assume any joint venture liabilities or to provide a guarantee of either joint venture performance or any joint venture liability. Losses allocated to the noncontrolling interests represent an additional potential loss for the Company as the noncontrolling interests are not obligated to contribute assets to the joint venture to the extent they have a negative capital account, and depending on the ultimate outcome of the joint venture, the Company could potentially absorb all losses associated with the joint venture. From formation of the joint venture, August 3, 2012, through September 30, 2013, losses totaling \$667,000 have been allocated to the noncontrolling interests.

Note C. 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 is now open.

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.

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 nine month periods ended September 30, 2013 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, 2012.



## Overview 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). We no longer have any interest in or rights to Chrysalin. On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, (the "JV") to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

In 2012 we wound down internal operations, ceased clinical development of AZX100 in dermal scarring, formerly our principal drug candidate, and moved to a more virtual operating model. Certain manufacturing and regulatory activities related to AZX100 that are required either from a statutory perspective or for reporting purposes, will continue. We are also performing limited pre-clinical studies with AZX100 in fibrosis. We are currently seeking development partnering or licensing opportunities for AZX100 in dermal scarring, pulmonary fibrosis and peridural fibrosis.

The JV intends to implement an initial development plan to file an IND (USA) and a CTA (Canada) and pursue FDA approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012). 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 cholesterol. 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. For a description of the JV, please refer to Note B to our financial statements included in this Form 10-Q.

The Company intends to limit its internal operations in a virtual operating model while 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.

## Description of Current Peptide Drug Candidates

### 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 removed by heparin sulfate receptors in the liver. 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. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia, HoFH), or have Severe Refractory Hypercholesterolemia, AEM-28 may provide a therapeutic solution. Our joint venture has an Exclusive License Agreement with the University of Alabama Birmingham Research Foundation for AEM-28 and certain of its analogs.

### AZX100

AZX100 is a novel synthetic 24-amino acid peptide and is believed to have smooth muscle relaxation and anti-fibrotic properties. AZX100 has been 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.

## 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 14, 2013, for the year ended December 31, 2012 are those that depend most heavily on these judgments and estimates. As of September 30, 2013, there have been no material changes to any of the critical accounting policies contained in our Annual Report for the year ended December 31, 2012.

### Results of Operations Comparing Three-Month Period Ended September 30, 2013 to the Corresponding Period in 2012.

**General and Administrative (“G&A”) Expenses:** G&A expenses related to our ongoing operations were \$245,000 in the third quarter of 2013 compared to \$480,000 in the third quarter of 2012. Administration expenses declined due to a decrease in our lease expenses caused by a reduction in office space occupied effective March 1, 2013 and the reduction from four employees to two employees in the second quarter of 2012.

**Research and Development Expenses:** Research and development expenses were \$958,000 for the third quarter of 2013 compared to \$667,000 for the third quarter of 2012. Our research and development expenses increased in the third quarter of 2013 compared to the same period in 2012 due to the inclusion of operating expenses of LipimetiX Development, LLC, which totaled (net of intercompany transactions) \$840,000 for the three months ended September 30, 2013, and \$457,000 for the three months ended September 30, 2012.

**Net Loss:** We incurred a net loss in the third quarter of 2013 of \$1.2 million compared to a net loss of \$1.1 million in the third quarter of 2012. The Net Loss from 2013 benefited from the effect of the reduction in internal operations, but this beneficial effect was offset by inclusion of the operating expenses of LipimetiX Development, LLC. Net Loss in the third quarter includes operating expenses of LipimetiX Development, LLC, which totaled (net of intercompany transactions) \$840,000 for the three months ended September 30, 2013, and \$457,000 for the three months ended September 30, 2012.

### Results of Operations Comparing Nine-Month Period Ended September 30, 2013 to the Corresponding Period in 2012.

**General and Administrative (“G&A”) Expenses:** G&A expenses related to our ongoing operations were \$956,000 in the first nine months of 2013 compared to \$1,297,000 in the first nine months of 2012. Administration expenses declined due to a decrease in our lease expenses caused by a reduction in office space occupied effective March 1, 2013 and the reduction from four employees to two employees in the second quarter of 2012.

**Research and Development Expenses:** Research and development expenses were \$2,619,000 for the first nine months of 2013 compared to \$1,626,000 for the first nine months of 2012. Our research and development expenses increased in the first nine months in 2013 compared to the same period in 2012 primarily due to the operating expenses of LipimetiX Development, LLC, which totaled (net of intercompany transactions) \$2,255,000 for the nine months ended September 30, 2013, and \$457,000 for the nine months ended September 30, 2012.

Interest and Other Income, Net: Interest and Other Income, Net, increased from \$93,000 in the first nine months in 2012 to \$155,000 in first nine months of 2013 due to the receipt of \$152,000 in the first quarter of 2013 from the conversion of an insurance company, in which we were a policyholder, from mutual to private ownership, while the first nine months of 2012 included a gain of \$80,000 from the sale of lab equipment.

Net Loss: We incurred a net loss in the first nine months of 2013 of \$3.4 million compared to a net loss of \$2.8 million in the first nine months of 2012. The Net Loss from 2013 benefited from effect of the reduction in internal operations and receipt of \$152,000 in the first quarter of 2013 from the conversion of an insurance company, in which we were a policyholder, from mutual to private ownership, but these beneficial effects were offset by inclusion of the operating expenses of LipimetiX Development, LLC. Net Loss includes operating expenses of LipimetiX Development, LLC, which totaled (net of intercompany transactions) \$2,255,000 for the nine months ended September 30, 2013, and \$457,000 for the nine months ended September 30, 2012.

### Liquidity and Capital Resources

We have historically financed our operations through operating cash flows and 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 has been research and development of our product candidates. We received approximately \$100 million in cash from the sale of our 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. In 2011, we received an Arizona State income tax refund for the 2010 tax year of \$181,000. We also received additional Arizona State income tax refunds of \$158,000 in 2012 for the 2011 tax year and \$21,000 in 2013 for the 2012 tax year. We received net proceeds of \$4,612,000 from the exercise of stock options during our development stage period, \$176,000 from the sale of lab equipment and furniture and \$152,000 from the conversion of an insurance company, in which we were a policy holder, from mutual to private ownership.

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC (“JV”) to develop Apo E mimetic peptide molecule AEM-28 and its analogs and we contributed \$6.0 million to the Joint Venture. The Joint Venture has used \$3.5 million of its cash through September 30, 2013. At September 30, 2013, we had cash and cash equivalents of \$7.2 million, of which \$2.5 million is held in, and reserved for use by, LipimetiX Development, LLC and unavailable for general use by the Company.

If we continue our plan to limit internal operations in a virtual operating model in 2013, we currently estimate that we will expend in the range of \$4.0 million in 2013, which includes approximately \$2.5 million by LipimetiX Development LLC, and excludes litigation costs related to the qui tam action, which cannot be estimated at this time and could be significant. We expect that the joint venture will expend the \$6 million (\$2.5 million remaining at September 30, 2013) over its planned twenty-seven month development period. Currently our planned operations in 2013 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 its 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 September 30, 2013 will be sufficient to meet our presently projected cash and working capital requirements for the next twelve months. 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 14, 2013 and to Note C to our Financial Statements included 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, 2012.

##### 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)	November 12, 2013
/s/ Les M. Taeger Les M. Taeger	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	November 12, 2013

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

Capstone Therapeutics Corp.  
 (the "Company")  
 Exhibit Index to Quarterly Report on Form 10-Q  
 For the Quarterly Period Ended September 30, 2013

Exhibit No.	Description	Incorporated by Reference To:	Filed Herewith
10.1	Accounting Service Agreement Amendment #1, dated August 23, 2013		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 third quarter of fiscal year 2013, filed with the SEC on November 12, 2013 formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012, (ii) the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2013 and 2012 and the one hundred and ten months ended September 30, 2013, (iii) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 and 2012 and the one hundred and ten months ended September 30, 2013, and (iv) Notes to Unaudited Condensed Consolidated Financial Statements. *		

\* Furnished herewith