

Capstone Therapeutics Corp.  
Form 10-Q  
November 10, 2016

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, 2016

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 104, 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. Yes 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).

Yes No

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

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 November 1, 2016



**CAPSTONE THERAPEUTICS CORP.**

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## 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, 2015, 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 this section titled “Risks,” include, but are not limited to:

- effect of non-compliance with the Securities and Exchange Commission’s (“SEC”) Rules and Regulations requiring our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 30, 2016, to include an opinion of an Independent Public Accountant, and this Current Report on Form 10-Q to be reviewed by an Independent Public Accountant;
- failure of the Company, or its joint venture, LipimetiX Development, Inc., to obtain additional funds to continue operations;
- the impact of the terms or conditions of agreements associated with funds obtained to fund operations;
- failure to obtain additional funds required to complete clinical trials and supporting research and production efforts necessary to obtain FDA or comparable foreign agencies approval for product candidates or secure development agreements with pharmaceutical manufacturers;
- the impact of using 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 or comparable foreign agencies approvals;
- increased regulation by the FDA or comparable foreign 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; and
- failure to successfully implement our drug development strategy for AEM-28 and its analogs.

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. Any forward-looking statement you read in this Quarterly Report on Form 10-Q reflects our current views with respect to future events and is 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.****CONDENSED CONSOLIDATED BALANCE SHEETS***(in thousands, except share and per share data)**(Unaudited)*

	September 30, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$1,127	\$1,011
Other current assets	78	247
Total current assets	1,205	1,258
Patent license rights, net	392	509
Furniture and equipment, net	-	-
Total assets	\$1,597	\$1,767
<b>LIABILITIES AND EQUITY</b>		
Current liabilities		
Accounts payable	\$325	\$254
Other accrued liabilities	44	7
Total current liabilities	369	261
Convertible Promissory Notes Payable	1,000	1,000
Equity		
Capstone Therapeutics Corp. Stockholders' Equity		
Common Stock\$.0005 par value; 150,000,000 shares authorized; 40,885,411 shares in 2016 and 2015 issued and outstanding	20	20
Additional paid-in capital	189,474	189,442
Accumulated deficit	(189,266)	(188,956)
Total Capstone Therapeutics Corp. stockholders' equity	228	506
Noncontrolling interest	-	-
Total equity	228	506
Total liabilities and equity	\$1,597	\$1,767



See notes to unaudited condensed consolidated financial statements

**CAPSTONE THERAPEUTICS Corp.****CONDENSED CONSOLIDATED Statements of Operations***(in thousands, except per share data)***(Unaudited)**

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
<b>OPERATING EXPENSES</b>				
General and administrative	\$ 55	\$ 241	\$ 437	\$ 1,265
Research and development	446	175	823	808
Total operating expenses	501	416	1,260	2,073
Interest and other (income) expenses, net	20	19	56	28
Loss from continuing operations before taxes	521	435	1,316	2,101
Income tax benefit	(34 )	-	(60 )	(198 )
<b>NET LOSS</b>	<b>487</b>	<b>435</b>	<b>1,256</b>	<b>1,903</b>
Less: Net Loss attributable to the noncontrolling interest	(946 )	-	(946 )	-
Net Loss (Income) attributable to Capstone Therapeutics Corp. stockholders	\$ (459 )	\$ 435	\$ 310	\$ 1,903
Per Share Information:				
Net loss (income), basic and diluted, attributable to Capstone Therapeutics Corp. stockholders	\$ (0.01 )	\$ 0.01	\$ 0.01	\$ 0.05
Basic and diluted shares outstanding	40,885	40,885	40,885	40,885

See notes to unaudited condensed consolidated financial statements

**CAPSTONE THERAPEUTICS Corp.****CONDENSED CONSOLIDATED Statements of CASH FLOWS***(in thousands)***(Unaudited)**

	Nine months ended September 30,	
	2016	2015
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (310 )	\$ (1,903 )
Non cash items:		
Depreciation and amortization	134	117
Non-cash stock-based compensation	32	158
Reduction in JV losses recognized	(946 )	
Change in other operating items:		
Other current assets	152	195
Accounts payable	71	8
Other accrued liabilities	37	(102 )
Cash flows used in operating activities	(830 )	(1,527 )
<b>INVESTING ACTIVITIES</b>		
Cash flows provided by investing activities	-	-
<b>FINANCING ACTIVITIES</b>		
LipimetiX Development, Inc. Series B-1 Preferred Stock sale, net of issuance costs	946	-
Cash flows provided by financing activities	946	-
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>116</b>	<b>(1,527 )</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>1,011</b>	<b>2,164</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 1,127</b>	<b>\$ 637</b>

See notes to unaudited condensed consolidated financial statements

**CAPSTONE THERAPEUTICS CORP.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2016**

**Note A. OVERVIEW OF BUSINESS**

**Description of the Business**

Capstone Therapeutics Corp. (the “Company”, “we”, “our” or “us”) 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). Since March 2012, we no longer have any interest in or rights to Chrysalin. In 2012 we ceased clinical development of AZX100 in dermal scarring, formerly our principal drug candidate, and moved to a more virtual operating model. In 2014, we terminated the License Agreement for AZX100 intellectual property and returned all interest in and rights to the AZX100 intellectual property to the Licensor (AzTE).

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, (now LipimetiX Development, Inc.), (the “JV”), to develop Apo E mimetic peptide molecule AEM-28 and its analogs. The JV has a development plan to pursue regulatory approval of AEM-28, or an analog, as treatment for Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012), diabetic dyslipidemia, and other hyperlipidemic indications. The initial development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting reduction of cholesterol and triglycerides.

The JV received allowance from regulatory authorities in Australia permitting the JV to proceed with the planned clinical trials. The Phase 1a clinical trial commenced in Australia in April 2014 and the Phase 1b/2a clinical trial commenced in Australia in June 2014. The clinical trials for AEM-28 were randomized, double-blinded, placebo-controlled studies to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of six escalating single doses (Phase 1a in healthy patients with elevated cholesterol) and multiple ascending doses of the three highest doses from Phase 1a (Phase 1b/2a in patients with hypercholesterolemia and healthy volunteers with elevated cholesterol and high Body Mass Index). The Phase 1a clinical trial consisted of 36 patients and the Phase 1b/2a consisted of 15 patients. Both clinical trials were completed in 2014 and the Medical Safety Committee, reviewing all safety-related aspects of the clinical trials, observed a generally acceptable safety profile. As first-in-man studies, the primary endpoint was safety; yet efficacy measurements analyzing pharmacodynamics yielded statistical significance in the pooled dataset favoring AEM-28 versus placebo in multiple lipid biomarker endpoints.

Concurrent with the clinical development activities of AEM-28, the JV has performed pre-clinical studies that have identified an analog of AEM-28, referred to as AEM-28-14, and a new formulation, that has the potential of increased efficacy, higher human dose toleration and an extended composition of matter patent life (application filed with the U.S. Patent and Trademark Office in 2015). The JV's current intent is to prioritize the development of AEM-28-14.

The JV and the Company are exploring fundraising, partnering or licensing, to obtain additional funding to continue development activities of AEM-28 and its analogs, including AEM-28-14, and operations.

The JV and the Company do not have sufficient funding at this time to continue additional material development activities of AEM-28 and its analogs, including AEM-28-14. The JV may conduct future clinical trials in Australia, the USA, and other regulatory jurisdictions if regulatory approvals, additional funding, and other conditions permit.

The Company, funding permitting, intends to continue limiting its internal operations to a virtual operating model while monitoring and participating in the management of JV's AEM-28 and analogs development activities.

## **Description of Current Peptide Drug Candidates.**

### Chimeric Apo E Mimetic Peptide Molecule – AEM-28 and its analogs

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 and AEM-28 and its analogs, including AEM-28-14 is a 28 amino acid mimetic of Apo E (with an aminohexanoic acid group and a phospholipid), and both contain a domain that anchors into a lipoprotein surface while also providing the Apo E receptor binding domain, which allows clearance through the heparan sulfate proteoglycan (HSPG) receptors (Syndecan-1) in the liver. AEM-28 and its analogs, including AEM-28-14, as Apo E mimetics, have 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 and its analogs, including AEM-28-14. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia-HoFH), or have hypercholesterolemia or hypertriglyceridemia, AEM-28 and its analogs may provide a therapeutic solution. Our joint venture has an Exclusive License Agreement with the University of Alabama at Birmingham Research Foundation for AEM-28 and certain of its analogs.

## **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." In November 2003, we sold our Bone Device Business.

In August 2004, we purchased substantially all of the assets and intellectual property of Chrysalis Biotechnology, Inc., including its exclusive worldwide license for Chrysalin, a peptide, for all medical indications. Subsequently, our efforts were focused on research and development of Chrysalin with the goal of commercializing our products in fresh fracture healing. (In March 2012, we returned all rights to the Chrysalin intellectual property and no longer have any interest in, or rights to, Chrysalin.)

In February 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, an anti-fibrotic peptide. In 2014, we terminated the License Agreement with AzTE (Licensor) for the core intellectual property relating to AZX100 and returned all interest in and rights to the AZX100 intellectual property to the Licensor.

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

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 joint venture or “JV”, refer to LipimetiX Development, Inc. (formerly LipimetiX Development, LLC).

### **Financial Statement Presentation and Management’s Plan**

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 report from our Independent Registered Public Accounting Firm on our consolidated financial statements for the year ended December 31, 2014 included in our Annual Report on Form 10-K expressed substantial doubt about the Company’s ability to continue as a going concern. The Company did not engage an Independent Registered Public Accounting Firm to audit and express an opinion on our consolidated financial statements for the year ended December 31, 2015, or to review this Current Report on form 10-Q.

Management has determined that the Company and our JV will require additional capital above its current cash and working capital balances to further develop AEM-28 and its analogs or continue operations. Accordingly, the Company has reduced its development activities. The Company’s corporate strategy is to raise funds by possibly engaging in a strategic/merger transaction, or conducting a private or public offering of debt or equity securities for capital. These financial statements do not include any adjustments that might result from the outcome of the uncertainty of the Company successfully implementing its corporate strategy.

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 64% owned subsidiary, LipimetiX Development, Inc. 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, 2015.

### **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**

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.

## **Joint Venture Accounting**

The Company entered into a joint venture in 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 until common ownership equity was reduced to \$0. Subsequent joint venture losses were being allocated to the Series A preferred ownership equity (100% Company). Subsequent to March 31, 2013, all joint venture losses had been allocated to the Company. On August 25, 2016 the JV raised \$1,012,000 (\$946,000 net of issuance costs) in a Series B-1 Preferred Stock and Warrant offering. As of September 30, 2016, losses incurred by the JV exceed the capital accounts of the JV. The Company has a revolving loan agreement with the joint venture to advance the joint venture funds for operations in an amount not to exceed a net (net of expected tax credits or other funds obtained) of \$1,600,000, with the net amount due December 31, 2016. Losses incurred by the joint venture in excess of the capital accounts of the joint venture will be allocated to the Company to the extent of net outstanding advances. The additional JV capital from the Series B-1 Preferred Stock and Warrant offering resulted in a decrease of \$946,000 in previously recognized losses of the JV by the Company, which had been recognized by the Company because of the existence of the outstanding revolving loan.

## **Cash and Cash Equivalents**

At September 30, 2016, cash and cash equivalents included money market accounts.

## **Recent Accounting Pronouncements**

In August 2014, the Financial Accounting Standards Board issued Accounting Standard Update (“ASU”) No. 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40)* (“Update”): *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern, providing a requirement under U.S. GAAP for an entity’s management to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date the financial statements are issued; and if those conditions exist, to disclose that fact, the conditions and the potential effects on the entity’s ability to meet its obligations. The Update will be effective for an annual period ending after December 15, 2016, with early application permitted.* We have not elected early application. However, if additional funds are not obtained to continue the development of AEM-28 or its analogs, or operations, it will impair our ability to continue as a going concern. If we do not continue as a going concern, the Company may incur additional losses, up to, and possibly exceeding our net joint venture investment and revolving loan balance.

**Note JOINT VENTURE FOR DEVELOPMENT OF APO E MIMETIC PEPTIDE MOLECULE AEM-28  
B. 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 its analogs. In June 2015, the JV converted from a limited liability company to a corporation, LipimetiX Development, Inc. The Company contributed \$6 million, which included \$1 million for 600,000 voting common ownership units (now common stock), representing 60% ownership in the JV, and \$5 million for 5,000,000 non-voting preferred ownership units (now preferred stock), which have preferential distribution rights. On March 31, 2016, the Company converted 1,500,000 shares of its preferred stock into 120,000 shares of common stock, increasing its common stock ownership from 60% to 64%. As discussed below, the JV Series B-1 Preferred Stock issuance, because of the participating and conversion features of the preferred stock, effectively reduces the Company’s ownership in the JV to 59.3%.

LipimetiX, LLC contributed all intellectual property rights for Apo E mimetic molecules it owned and assigned its Exclusive License Agreement between The University of Alabama at Birmingham Research Foundation (“UABRF”) and LipimetiX, LLC, for the UABRF intellectual property related to Apo E mimetic molecules AEM-28 and its analogs to the JV, in return for 400,000 voting common ownership units (now common stock) representing 40% ownership in JV (now 36%), and \$378,000 in cash (for certain initial patent-related costs and legal expenses).

On August 25, 2016, LipimetiX Development, Inc. closed a Series B-1 Preferred Stock offering, raising funds of \$1,012,000 (\$946,000 net of issuance costs of approximately \$66,000). Individual accredited investors and management participated in the financing. This initial closing of the Series B-1 preferred stock offering resulted in the issuance of 94,537 shares of preferred stock, convertible to an equal number of the JV’s common stock at the election of the holders, and warrants to purchase an additional 33,088 shares of JV preferred stock, at an exercise price of \$10.70, with a ten-year term. The preferred stock represents 7.8% of the post-closing common stock of the JV, on an “as-converted” basis. Following this initial Series B-1 closing, on an “as converted” basis, the Company owns 59.3% of the JV.

In connection with the Series B-1 financing, the JV entered into the Series B Preferred Stock and Warrant Purchase Agreement. The Series B Preferred Stock and Warrant Purchase Agreement allows for issuance of up to an additional 45,640 Series B-1 preferred stock and 15,975 preferred stock warrants at the same terms as the current Series B-1 preferred stock and warrants, and up to 1,200,000 additional Series B-2 preferred stock, at terms yet to be determined. Series B preferred stock is a participating preferred stock. As a participating preferred, the preferred stock will earn a 5% dividend, payable only upon the election by the JV or in liquidation. Prior to the JV common stock holders receiving distributions, the participating preferred stockholders will receive their earned dividends and payback of their original investment. Subsequently, the participating preferred will participate in future distributions on an equal “as converted” share basis with common stock holders. The Series B preferred stock has “as converted” voting rights and other terms standard to a security of this nature.

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 I. Goldberg, Ph.D., Phillip M. Friden, Ph.D. and Eric M. Morrel, Ph.D. The Exclusive License Agreement, as amended, 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 2035. The Agreement, as amended, also calls for annual maintenance payments of \$25,000, various milestone payments of \$50,000 to \$500,000 and minimum royalty payments of \$500,000 to \$1,000,000 per year commencing on January 1 of the first calendar year following the year in which the First Commercial Sale occurs. UABRF will also be paid 5% of Non-Royalty Income received.

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 established a Joint Development Committee (“JDC”) to manage JV development activities. Upon conversion by the JV from a limited liability company to a corporation, the parties entered into a Stockholders Agreement for the JV, and the JDC was replaced by a Board of Directors (JV Board). The JV Board is composed of three members appointed by the non-Company ownership group, two members appointed by the Company and one member appointed by the Series B-1 Preferred Stockholders. 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, and approval of annual budgets, will be decided by a majority vote of the common and series B-1 Preferred Stock (voting on an “as converted” basis) stockholders.

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 services related to these agreements have been completed and new Management and Accounting Services Agreements were entered into effective June 1, 2016. The new monthly management fee is \$80,000 and the new monthly accounting services fee is \$10,000. However, no Management or Accounting Services fees are due or payable except to the extent funding is available, as unanimously approved by members of the JV Board of Directors and as reflected in the approved operating budget in effect at that time. In connection with the Series B-1 Preferred Stock issuance, Management Fees totaling \$300,000 and Accounting Fees totaling \$60,000 have been authorized for 2016.

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 originally, now 64% Company / 36% noncontrolling interests). However, for the Company’s consolidated financial statement, joint venture losses were recorded on the basis of common ownership equity interests until common ownership equity was reduced to \$0. Subsequent joint venture losses were being allocated to the Series A preferred ownership equity (100% Company). Subsequent to March 31, 2013, all joint venture losses had been allocated to the Company. On August 25, 2016 the JV raised \$1,012,000, (\$946,000 net of issuance costs) in a Series B-1 Preferred Stock and Warrant offering. As of September 30, 2016,

losses incurred by the JV exceed the capital accounts of the JV. The Company has a revolving loan agreement with the joint venture to advance the joint venture funds for operations in an amount not to exceed a net (net of expected tax credits or other funds obtained) of \$1,600,000, with the net amount due December 31, 2016. Losses incurred by the joint venture in excess of the capital accounts of the joint venture will be allocated to the Company to the extent of net outstanding advances. The additional JV capital from the Series B-1 Preferred Stock offering resulted in a decrease of \$946,000 in previously recognized losses of the JV by the Company, which had been recognized by the Company because of the existence of the outstanding revolving loan. At September 30, 2016, outstanding advances on the revolving loan agreement totaled \$1,574,000.

The joint venture incurred net operating expenses, prior to the elimination of intercompany transactions, of \$814,000 in the nine-month period ended September 30, 2016 and \$8,204,000 for the period from August 3, 2012 (inception) to September 30, 2016, of which \$814,000, prior to the previously described reduction in losses recognized of \$946,000, and \$6,592,000, respectively, have been recorded by 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, 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, 2016, losses totaling \$667,000 have been allocated to the noncontrolling interests. If the joint venture or Company is unable to obtain additional funding, the ability of the joint venture to continue development of AEM-28 and its analogs, including AEM-28-14, would be impaired as would the joint venture's ability to continue operations. If the joint venture does not continue as a going concern, at September 30, 2016 the Company would incur an additional loss of \$667,000 for the joint venture losses allocated to the noncontrolling interests.

**Note C. NOTE PAYABLE – FUNDRAISING ACTIVITIES**

As disclosed above, management has determined that the Company will require additional capital above its current cash and working capital balances to further develop AEM-28 and its analogs and to continue operations. Accordingly, the Company has reduced its development activities. The Company's corporate strategy is to raise funds either by the Company, or directly in its joint venture, by possibly engaging in a strategic/merger transaction, or conducting a private or public offering of debt or equity securities for capital.

On December 11, 2015, we entered into a Securities Purchase Agreement (the "Agreement") with Biotechnology Value Fund affiliated entities Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P., Investment 10, LLC, and MSI BVF SPV, LLC (the "Lenders"), to provide short-term funding for our operations. A portion of the funds have been advanced to JV to initiate preclinical development activities for our lead commercial drug candidate, AEM-28-14. The Lenders, at September 30, 2016 and December 31, 2015, owned in the aggregate, approximately 19% of our outstanding Common Stock.

Pursuant to the Agreement, the Lenders funded an aggregate of \$1,000,000 of loans to us, evidenced by Convertible Promissory Notes (the "Notes") dated December 11, 2015 and due April 30, 2017. The Notes bear interest at 5% per annum and are secured by a security interest in all of our assets.



The unpaid principal amount of the Notes will convert automatically upon the closing of a Qualified Equity Financing, which is defined in the Agreement as an offering of equity securities with aggregate gross proceeds of at least \$5,000,000 including the principal of any converted Notes. Such conversion will be into the same securities and on the same terms as provided for the other investors in the Qualified Equity Financing.

As a Qualified Equity Financing was not consummated by March 31, 2016, the unpaid principal amount of the Notes may be converted, at the election of the Lenders, into shares of Common Stock, at a conversion price (the "Optional Conversion Price") equal to the trailing 10-day weighted average trading price of the Common Stock, but not be less than \$.135 or more than \$.18 per share. Upon a change in control of the Company, the Lenders may elect to accelerate the Notes or convert them into Common Stock at a conversion price equal to the Optional Conversion Price.

Under the Agreement, the Lenders have the right to elect to acquire, upon conversion of the Notes, convertible preferred stock rather than Common Stock, such preferred stock to vote with the Common Stock and to be convertible into the equivalent number of shares of Common Stock as would have been originally issued if the Notes conversion had been into Common Stock. Such preferred shares would have no preferential liquidation or distribution rights and would not have any dividend or preferred return rights.

#### **Note D. Australian Refundable Research & Development Credit**

In March 2014, LipimetiX Development LLC, (see Note B) formed a wholly-owned Australian subsidiary, Lipimetix Australia Pty Ltd, to conduct Phase 1a and Phase1b/2a clinical trials in Australia. Currently Australian tax regulations provide for a refundable research and development tax credit equal to 45% of qualified expenditures. Subsequent to the end of its Australian tax years, Lipimetix Australia Pty, Ltd intends to submit claims for a refundable research and development tax credit. The transitional Australian tax periods/years granted for Lipimetix Australia Pty, Ltd end on June 30, 2014, December 31, 2014 and thereafter December 31 of each succeeding year. For the tax year ended June 30, 2014, Lipimetix Australia Pty, Ltd received a refundable research and development tax credit of AUD\$227,000. For the tax year ended December 31, 2014 Lipimetix Australia Pty, Ltd, received a refundable research and development tax credit of AUD\$301,000. At December 31, 2015, a refundable research and development tax credit of AUD\$189,000 was recorded and the refund was received in June 2016. At September 30, 2016, an additional AUD\$60,000 (USA \$ 47,000) was recorded and at September 30, 2016, the refundable research and development tax credit is included in other current assets.

#### **Note Contingency – Non-Compliance with Securities and Exchange Commission Reporting Requirements and E: OTCQB Market Requirements**

Our current level of funds available for operation has led to additional cost cutting, which included the decision to not engage an independent public accountant to audit and express an opinion on our December 31, 2015 financial statements included in our Annual Report on Form 10-K filed with the SEC on March 30, 2016, or to review this Current Report on Form 10-Q, as required by current SEC rules and regulations, and as required to be listed on the OTCQB Market. We cannot currently predict the response to these actions by the SEC or the OTCQB Market, nor the effects of their actions, including the possible effect on the trading of our common stock. The decision to not engage an independent public accountant to audit and express an opinion on our December 31, 2015 financial statements or review this Current Report on Form 10-Q could have a material adverse effect on the Company and its Stockholders.

#### **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, 2016 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, 2015.

## 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). Since March 2012, we no longer have any interest in or rights to Chrysalin. In 2012 we ceased clinical development of AZX100 in dermal scarring, formerly our principal drug candidate, and moved to a more virtual operating model. In 2014, we terminated the License Agreement for AZX100 intellectual property and returned all interest in and rights to the AZX100 intellectual property to the Licensor (AzTE).

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, (now LipimetiX Development, Inc.) (the “JV”) to develop Apo E mimetic peptide molecule AEM-28 and its analogs. The JV has a development plan to pursue regulatory approval of AEM-28, or an analog, as treatment for Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012), diabetic dyslipidemia and other hyperlipidemic indications. The initial development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting reduction of cholesterol and triglycerides.

The JV received allowance from regulatory authorities in Australia permitting the JV to proceed with the planned clinical trials. The Phase 1a clinical trial commenced in Australia in April 2014 and the Phase 1b/2a clinical trial commenced in Australia in June 2014. The clinical trials for AEM-28 are randomized, double-blinded, placebo-controlled studies to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of six escalating single doses (Phase 1a in healthy patients with elevated cholesterol) and multiple ascending doses of the three highest doses from Phase 1a (Phase 1b/2a in patients with Hypercholesterolemia and normal healthy volunteers with elevated cholesterol and high Body Mass Index). The Phase 1a clinical trial consisted of 36 patients and the Phase 1b/2a consisted of 15 patients. Both clinical trials were completed in 2014 and the Medical Safety Committee, reviewing all safety-related aspects of the clinical trials, observed a generally acceptable safety profile. As first-in-man studies, the primary endpoint was safety; yet efficacy measurements analyzing pharmacodynamics yielded statistical significance in the pooled dataset favoring AEM-28 versus placebo in multiple lipid biomarker endpoints.

Concurrent with the clinical development activities of AEM-28, the JV has performed pre-clinical studies that have identified an analog of AEM-28, referred to as AEM-28-14, and a new formulation, that has the potential of increased efficacy, higher human dose toleration and an extended patent life (application filed in 2015). The JV’s current intent is to prioritize the development of AEM-28-14.

The JV and Company are exploring fundraising, partnering or licensing to obtain additional funding to continue development activities of AEM-28 and its analogs, including AEM-28-14, and operations.

The JV and the Company do not have sufficient funding at this time to continue additional material development activities of AEM-28 and its analogs, including AEM-28-14. The JV may conduct future clinical trials in Australia, the USA, and other regulatory jurisdictions if regulatory approvals, additional funding, and other conditions permit. The JV may also fund research or studies to investigate AEM-28-14 for treatment of acute coronary syndrome and other indications.

The Company, funding permitting, intends to limit its internal operations to a virtual operating model while continuing monitoring and participating in the management of JV's AEM-28 and analogs development activities.

## **Description of Our Peptide Drug Candidate.**

### Chimeric Apo E Mimetic Peptide Molecule – AEM-28 and its analogs

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 and AEM-28-14 (an analog of AEM-28) is a 28 amino acid mimetic of Apo E (with an aminohexanoic acid group and a phospholipid) and both contain a domain that anchors into a lipoprotein surface while also providing the Apo E receptor binding domain, which allows clearance through the heparan sulfate proteoglycan (HSPG) receptors (Syndecan-1) in the liver. AEM-28 and AEM-28-14, as Apo E mimetics, have 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 and AEM-28-14. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia-HoFH), or have hypercholesterolemia or hypertriglyceridemia, AEM-28 or AEM-28-14 may provide a therapeutic solution. Our joint venture has an Exclusive License Agreement with the University of Alabama at Birmingham Research Foundation for AEM-28 and certain of its analogs.

## **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 30, 2016, for the year ended December 31, 2015 are those that depend most heavily on these judgments and estimates. As of September 30, 2016, there have been no material changes to any of the critical accounting policies contained in our Annual Report for the year ended December 31, 2015.

## **Results of Operations Comparing Three-Month Period Ended September 30, 2016 to the Corresponding Period in 2015.**

*General and Administrative (“G&A”) Expenses:* G&A expenses related to our ongoing operations were \$55,000 in the third quarter of 2016 compared to \$241,000 in the third quarter of 2015. Administration expenses decreased primarily due to a 50% reduction in salaries and consulting fee rates taken by all staff and consultants in March 2016, reduced professional fees and insurance costs from our decision to not engage an Independent Public Accountant to audit our December 31, 2015 financial statements or review our 2016 quarterly financial statements, and reduction of our insurance coverage, as part of our cost cutting efforts.

*Research and Development Expenses:* Research and development expenses were \$446,000 for the third quarter of 2016 compared to \$175,000 for the third quarter of 2015. Our research and development expenses in the third quarter reflect increased spending due to funds from the JV Series B-1 Preferred Stock and Warrant offering in August 2016. Our development activities of AEM-28 and its analogs, including AEM-28-14 will be limited, as we attempt to obtain additional funding.

*Net Loss attributable to Capstone Therapeutics stockholders:* We incurred a net income in the third quarter of 2016 of \$.5 million compared to a net loss of \$.4 million in the third quarter of 2015. Net losses were comparable between periods prior to the \$946,000 reduction in losses recorded (now allocated to noncontrolling interests) due to the JV Series B-1 Preferred Stock and Warrant offering in August 2016. Our operations and the development activities of AEM-28 and its analogs, including AEM-28-14 will be limited, as we attempt to obtain additional funding.

**Results of Operations Comparing Nine-Month Period Ended September 30, 2016 to the Corresponding Period in 2015.**

*General and Administrative (“G&A”) Expenses:* G&A expenses related to our ongoing operations were \$437,000 in the nine months ended September 30, 2016 compared to \$1,265,000 in the nine months ended September 30, 2015. Administration expenses decreased primarily due to a 50% reduction in salaries and consulting fee rates taken by all staff and consultants in March 2016 reduced professional fees and insurance costs from our decision to not engage an Independent Public Accountant to review our 2016 quarterly financial statements, and reduction of our insurance coverage, as part of our cost cutting efforts.

*Research and Development Expenses:* Research and development expenses were \$823,000 in the nine months ended September 30, 2016 compared to \$808,000 in the nine months ended September 30, 2015. Our development activities of AEM-28 and its analogs, including AEM-28-14 will be limited, as we attempt to obtain additional funding.

*Net Loss attributable to Capstone Therapeutics stockholders:* We incurred a net loss in the in the nine months ended September 30, 2016 of \$0.3 million, which included a \$0.9 million reduction in losses recorded (now allocated to noncontrolling interests) due to the JV Series B-1 Preferred Stock and Warrant offering in August 2016, compared to a net loss of \$1.9 million in the nine months ended September 30, 2015. Net loss has declined as we have significantly reduced our operations and the development activities of AEM-28 and its analogs, including AEM-28-14, as we attempt to obtain additional funding.

#### Liquidity and Capital Resources

With the sale of our Bone Device Business in November 2003, we sold all of our revenue producing operations. Since that time, we have primarily relied on our cash and investments to finance all our operations, the focus of which has been research and development of our product candidates.

On August 3, 2012, we entered into a joint venture, to develop Apo E mimetic peptide molecule AEM-28 and its analogs. We contributed \$6.0 million and through September 30, 2016 we have loaned an additional \$1,574,000 to the JV. The JV raised \$1,012,000 (\$946,000 net of issuance costs) in the JV’s Series B-1 Preferred Stock and Warrant offering in August 2016. At September 30, 2016, we had cash and cash equivalents of \$1,127,000, of which \$735,000 is held by our JV.

We intend to continue limiting our internal operations to a virtual operating model in 2016, however, without additional funding, we will not continue development of AEM-28 and its analogs, including AEM-28-14, past completion of the limited projects currently under way. Lack of additional funding within the next 12 months, would



impair our ability to continue our current operations and our ability to continue as a going concern.

Funding permitting, our planned operations in 2016 consist of continuing monitoring and participating in the management of the JV's AEM-28 and its analogs, including AEM-28-14, development activities.

Our future research and development and other expenses will vary significantly from prior periods and depend on the Company's decisions on future JV operations and obtaining additional funding.

We will require additional funds if we chose to extend the development of AEM-28 and its analogs or to continue operations. We cannot currently predict the amount of funds that will be required if we chose to extend the development activities of AEM-28 and its analogs and to continue operations. In any event, to complete the clinical trials and supporting research and production efforts necessary to obtain FDA or comparable foreign agencies' approval for product candidates would require us to obtain 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.

As discussed in Note C to the Financial Statement included in this Quarterly Report on Form 10-Q, the Company received loans totaling \$1,000,000 from entities that currently own approximately 19% of the Company's common stock. If not converted into shares of the Company's common stock, the loans would be due April 30, 2017.

#### 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**

None

**Item 6. Exhibits**

See the Exhibit Index following this report.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**CAPSTONE THERAPEUTICS CORP.**

(Registrant)

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ John M. Holliman, III John M. Holliman, III	Chairman and Chief Executive Officer (Principal Executive Officer)	November 10, 2016
/s/ Les M. Taeger Les M. Taeger	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	November 10, 2016

**Capstone Therapeutics Corp.**

(the "Company")

**Exhibit Index to Quarterly Report on Form 10-Q**

For the Quarterly Period Ended September 30, 2016

No.	Description	Incorporated by Reference To:	Filed Herewith
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 2016, filed with the SEC on November 10, 2016 formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015, (ii) the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2016 and 2015 (iii) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015, and (iv) Notes to Unaudited Condensed Consolidated Financial Statements.		X

\* Furnished herewith