

Capstone Therapeutics Corp.  
Form 10-Q  
November 09, 2015

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, 2015

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-21214

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

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

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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 October 31, 2015



**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, 2014, 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, 2014, and our Form S-1 filed with the Securities and Exchange Commission on June 26, 2015, as amended, include, but are not limited to:

- Failure to obtain additional funds to continue operations;
- the impact of the terms or conditions of agreements associated with funds obtained to fund operations;
- the impact of our actions to preserve cash including implementation of a virtual operating model;
- unfavorable results of product candidate development efforts, including through our joint venture;
- unfavorable results of pre-clinical or clinical testing, including through our joint venture;
- 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 and its analogs; and failure to obtain additional funds required to complete clinical trials and supporting research and production efforts
- necessary to obtain FDA, or comparable foreign agency, approval for product candidates or secure development agreements with pharmaceutical manufacturers.

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.****CONDENSED CONSOLIDATED BALANCE SHEETS***(in thousands, except share and per share data)*

|   | September<br>30,<br>2015<br>(unaudited) | December<br>31,<br>2014 |
|---|---|-------------------------|
| <b>ASSETS</b>   |   |                         |
| Current assets  |   |                         |
| Cash and cash equivalents   | \$ 637                                  | \$ 2,164                |
| Other current assets  | 360                                     | 555                     |
| Total current assets  | 997                                     | 2,719                   |
| Patent license rights, net  | 549                                     | 666                     |
| Furniture and equipment, net  | -                                       | -                       |
| Total assets  | \$ 1,546                                | \$ 3,385                |
| <b>LIABILITIES AND EQUITY</b>   |   |                         |
| Current liabilities   |   |                         |
| Accounts payable  | \$ 132                                  | \$ 124                  |
| Other accrued liabilities   | 56                                      | 158                     |
| Total current liabilities   | 188                                     | 282                     |
| Equity  |   |                         |
| Capstone Therapeutics Corp. Stockholders' Equity  |   |                         |
| Common Stock \$.0005 par value; 150,000,000 shares authorized;<br>40,885,411 shares in 2015 and 2014 issued and outstanding | 20                                      | 20                      |
| Additional paid-in capital  | 189,426                                 | 189,268                 |
| Accumulated deficit   | (188,088)                               | (186,185)               |
| Total Capstone Therapeutics Corp. stockholders' equity  | 1,358                                   | 3,103                   |
| Noncontrolling interest   | -                                       | -                       |
| Total equity  | 1,358                                   | 3,103                   |
| Total liabilities and equity  | \$ 1,546                                | \$ 3,385                |

*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<br>ended September<br>30, |              | Nine months ended<br>September 30, |              |
|--|--|--------------|------------------------------------|--------------|
|  | 2015                                   | 2014         | 2015                               | 2014         |
| <b>OPERATING EXPENSES</b>  |  |              |                                    |              |
| General and administrative   | \$241                                  | \$373        | \$1,265                            | \$1,047      |
| Research and development   | 175                                    | 865          | 808                                | 2,667        |
| Total operating expenses   | 416                                    | 1,238        | 2,073                              | 3,714        |
| Interest and other expenses (income), net  | 19                                     | (4 )         | 28                                 | (67 )        |
| Loss from operations before taxes  | 435                                    | 1,234        | 2,101                              | 3,647        |
| Income tax benefit   | -                                      | -            | (198 )                             | -            |
| <b>NET LOSS</b>  | <b>435</b>                             | <b>1,234</b> | <b>1,903</b>                       | <b>3,647</b> |
| Less: Net Loss attributable to the noncontrolling interest                           | -                                      | -            | -                                  | -            |
| Net Loss attributable to Capstone Therapeutics Corp. stockholders                    | \$435                                  | \$1,234      | \$1,903                            | \$3,647      |
| <b>Per Share Information:</b>  |  |              |                                    |              |
| Net loss, basic and diluted, attributable to Capstone Therapeutic Corp. stockholders | \$0.01                                 | \$0.03       | \$0.05                             | \$0.09       |
| 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<br>ended<br>September 30,<br>2015      2014 |                |
|---|---|----------------|
| <b>OPERATING ACTIVITIES</b>                           |   |                |
| Net loss  | \$(1,903)   | \$(3,647)      |
| Non cash items:                                       |   |                |
| Depreciation and amortization                         | 117   | 121            |
| Non-cash stock compensation                           | 158   | 52             |
| Change in other operating items:                      |   |                |
| Other current assets                                  | 195   | (44 )          |
| Accounts payable                                      | 8   | 137            |
| Other accrued liabilities                             | (102 )  | 234            |
| Cash flows used in operating activities               | (1,527)   | (3,147)        |
| <b>INVESTING ACTIVITIES</b>                           |   |                |
| Cash flows provided by investing activities           | -   | -              |
| <b>FINANCING ACTIVITIES</b>                           |   |                |
| Cash flows provided by financing activities           | -   | -              |
| <br>  |   |                |
| <b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>      | <b>(1,527)</b>  | <b>(3,147)</b> |
| <b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b> | <b>2,164</b>  | <b>6,258</b>   |
| <b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>       | <b>\$637</b>  | <b>\$3,111</b> |

*See notes to unaudited condensed consolidated financial statements*

**CAPSTONE THERAPEUTICS CORP.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2015**

**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 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. 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), Acute Hypertriglyceridemic Pancreatitis, 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 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 with 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 phospholipid formulation, that has the potential of equivalent 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 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.**

#### 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), have acute pancreatitis, or have hypercholesterolemia, 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.

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 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 60% 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, 2014. Information presented as of December 31, 2014 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**

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 (60% Company / 40% noncontrolling interests) until common ownership equity was reduced to \$0. Subsequent joint venture losses are being allocated to the preferred ownership equity (100% Company). Subsequent to March 31, 2013, all joint venture losses are being allocated to the Company. 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 \$700,000, with the net amount due December 31, 2015. 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.

## **Cash and Cash Equivalents**

At September 30, 2015, 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.

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, 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 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 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, and approval of annual budgets, will be decided by a majority vote of the common 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 current accounting services fee is \$1,000 a month. Commencing in November 2014, and ending in March 2015, Benu received a reduced monthly management fee in the amount of \$35,000. Subsequent to March 2015, no management fee has been paid to Benu for their services.

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 have been allocated to the Company. 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 \$700,000, with the net amount due December 31, 2015. 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. At September 30, 2015, outstanding advances on the revolving loan agreement totaled \$759,000.

The joint venture incurred net operating expenses, prior to the elimination of intercompany transactions, of \$503,000 in the nine month period ended September 30, 2015 and \$6,738,000 for the period from August 3, 2012 (inception) to September 30, 2015, of which \$503,000 and \$6,071,000, 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 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, 2015, 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, 2015 the Company would incur an additional loss of \$667,000 for the joint venture losses allocated to the noncontrolling interests.

#### **Note C. 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 by possibly engaging in a strategic/merger transaction, or conducting a private or public offering of debt or equity securities for capital. In connection with these efforts, we filed a Registration Statement on Form S-1 with the Securities and Exchange Commission on June 26, 2015, as amended, in connection with our contemplated public offering of shares of our Common Stock. The Registration Statement is not effective as of September 30, 2015.

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As of September 30, 2015, we have deferred recognition of approximately \$148,000 of direct costs, primarily legal costs and filing fees, related to fundraising activities in connection with our contemplated public offering of shares of our Common Stock. These costs are to be offset against the equity raised upon completion of the offering. The deferred costs are included in other current assets in the Condensed Consolidated Balance Sheet at September 30, 2015.

## **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 Phase 1b/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. At December 31, 2014 a AUD\$242,000 development tax credit was recorded by Lipimetix Australia Pty, Ltd, and at September 30, 2015, AUD\$202,000 has been accrued, as it is more likely than not that the recorded refundable research and development tax credit will be approved and received. At September 30, 2015, and December 31, 2014, AUD\$202,000 (US\$142,000), and AUD\$242,000 (US\$196,000), respectively, have been accrued and are included in other current assets in our condensed consolidated balance sheets.

## **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 month period ended September 30, 2015 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, 2014 and our Form S-1 filed with the Securities and Exchange Commission on June 26, 2015, as amended.

### **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 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. 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), Acute Hypertriglyceridemic Pancreatitis, 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 have 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 phospholipid formulation, that has the potential of equivalent 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 and maintaining the required level of corporate governance and reporting required to comply with Securities and Exchange Commission rules and regulations.

### **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), have acute pancreatitis, or have hypercholesterolemia, 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 16, 2015, for the year ended December 31, 2014 are those that depend most heavily on these judgments and estimates. As of September 30, 2015, there have been no material changes to any of the critical accounting policies contained in our Annual Report for the year ended December 31, 2014.

**Results of Operations Comparing Three-Month Period Ended September 30, 2015 to the Corresponding Period in 2014.**

*General and Administrative (“G&A”) Expenses:* G&A expenses related to our ongoing operations were \$241,000 in the third quarter of 2015 compared to \$373,000 in the third quarter of 2014. Administration expenses decreased primarily due to the deferral of approximately \$148,000 (see Note C) of direct fundraising costs (primarily legal costs and filing fees).

*Research and Development Expenses:* Research and development expenses were \$175,000 for the third quarter of 2015 compared to \$865,000 for the third quarter of 2014. Our research and development expenses varied in the third quarter of 2015 compared to the same period in 2014 primarily due to the inclusion and fluctuation of operating expenses of the JV, which totaled (net of intercompany transactions) \$152,000 for the three months ended September 30, 2015, and \$790,000 for the three months ended September 30, 2014. As discussed above, we have significantly reduced our development activities of AEM-28 and its analogs, including AEM-28-14, as we attempt to obtain additional funding.

*Net Loss attributable to Capstone Therapeutics stockholders:* We incurred a net loss in the third quarter of 2015 of \$0.4 million compared to a net loss of \$1.2 million in the third quarter of 2014. Net loss is affected by the items discussed above in General and Administrative Expenses, and the inclusion of the operating expenses of JV, which totaled (net of intercompany transactions) \$152,000 for the three months ended September 30, 2015 and \$790,000 for the three months ended September 30, 2014. As discussed above, we have significantly reduced our development activities of AEM-28 and its analogs, including AEM-28-14, as we attempt to obtain additional funding.

**Results of Operations Comparing Nine-Month Period Ended September 30, 2015 to the Corresponding Period in 2014.**

*General and Administrative (“G&A”) Expenses:* G&A expenses related to our ongoing operations were \$1,265,000 in 2015 compared to \$1,047,000 in 2014. Administration expenses increased primarily due to costs related to the *qui tam* litigation (settled for a one-time payment of \$50,000 in the second quarter of 2015) and investor relations activities. We expect that we may have elevated general and administrative costs, compared to 2014 levels, while we continue fund raising activities.

*Research and Development Expenses:* Research and development expenses were \$808,000 for 2015 compared to \$2,667,000 for 2014. Our research and development expenses varied in the first nine months of 2015 compared to the same period in 2014 primarily due to the inclusion and fluctuation of operating expenses of the JV, which totaled (net of intercompany transactions) \$499,000 for the nine months ended September 30, 2015, and \$2,195,000 for the nine months ended September 30, 2014. As discussed above, we have significantly reduced our development activities of AEM-28 and its analogs, including AEM-28-14, as we attempt to obtain additional funding.

*Interest and Other Expenses (Income), Net:* Interest and Other Expenses (Income), Net, decreased from \$67,000 of Income in 2014 to \$28,000 of Expense in 2015 due to the receipt of \$60,000 in 2014 from the conversion of an insurance company, in which we were a policyholder, from mutual to private ownership, while in 2015 the Company incurred a foreign exchange loss of \$33,000 related to our joint venture's Australian activities.

*Income Tax Benefit:* Income tax benefit in 2015 consisted of a refundable Australian research and development tax credit, as described in Note D to the financial statements included in this Quarterly Report on Form 10-Q, related to our joint venture's Australian clinical trial activities.

*Net Loss attributable to Capstone Therapeutics stockholders:* We incurred a net loss in the first nine months of 2015 of \$1.9 million compared to a net loss of \$3.6 million in the first nine months of 2014. Net loss is affected by the items discussed above and the inclusion of the operating expenses of JV, which totaled (net of intercompany transactions) \$499,000 for the nine months ended September 30, 2015 and \$2,195,000 for the nine months ended September 30, 2014. As discussed above, we have significantly reduced our 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, 2015 we have loaned an additional \$759,000 to the JV. At September 30, 2015, we had cash and cash equivalents of \$637,000.

We intend to continue limiting our internal operations to a virtual operating model in 2015, 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. We are exploring strategic options for both the Company and our joint venture. 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 2015 consist of continuing monitoring and participating in the management of the JV's AEM-28 and its analogs, including AEM-28-14, 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 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 past the initial Phase 1a and Phase 1b/2a clinical trials 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.

#### 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.





**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>      |
|----------------------------------|--|------------------|
| <u>/s/ John M. Holliman, III</u> | Chairman and Chief Executive Officer                 |                  |
| John M. Holliman, III            | (Principal Executive Officer)                        | November 9, 2015 |
| <u>/s/ Les M. Taeger</u>         | Senior Vice President and Chief<br>Financial Officer | November 9, 2015 |
| Les M. Taeger                    | (Principal Financial and Accounting Officer)         |                  |

**Capstone Therapeutics Corp.**

(the "Company")

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

For the Quarterly Period Ended September 30, 2015

| No.  | Description  | Incorporated<br>by Reference<br>To: | Filed<br>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 2015, filed with the SEC on November 9, 2015 formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014, (ii) the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2015 and 2014, (iii) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014, and (iv) Notes to Unaudited Condensed Consolidated Financial Statements. |                                     | X                 |

\* Furnished herewith