

**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 June 30, 2019

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.)

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 (See <https://www.sec.gov> or [Capstonethx.com](http://Capstonethx.com)).

Yes  No

Indicate by check mark whether the registrant has submitted electronically, if any, every Interactive Data File required to be submitted 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 such files).  Yes  No

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

|                         |                                     |                           |                                     |
|-------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/>            | Accelerated filer         | <input type="checkbox"/>            |
| Non-accelerated filer   | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| Emerging growth company | <input type="checkbox"/>            |                           |                                     |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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.

54,385,411 shares of common stock outstanding as of August 1, 2019

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---------------------|-------------------|---|
| Common Stock        | CAPS              | OTCQB                                     |

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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, 2018, 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,” “potential,” “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:

- 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, including the Company’s Securities Purchase, Loan and Security Agreement;
- 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;
- failure of the Company’s common stock to continue to be listed at the OTCQB stock market; 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)*

|   | <b>June 30,</b>    | <b>December 31,</b> |
|---|--------------------|---------------------|
|   | <b>2019</b>        | <b>2018</b>         |
|   | <i>(Unaudited)</i> |                     |
| <b>ASSETS</b>   |                    |                     |
| Current assets  |                    |                     |
| Cash  | \$ 305             | \$ 1,341            |
| Other current assets  | 398                | 97                  |
| Total current assets  | 703                | 1,438               |
| Patent license rights, net  | -                  | 39                  |
| <b>Total assets</b>   | <b>\$ 703</b>      | <b>\$ 1,477</b>     |
| <b>LIABILITIES AND EQUITY</b>   |                    |                     |
| Current liabilities   |                    |                     |
| Accounts payable  | \$ 797             | \$ 245              |
| Other accrued liabilities   | 22                 | 1                   |
| Total current liabilities   | 819                | 246                 |
| Secured debt and accrued interest, net of unamortized issuance costs  | 2,644              | 2,475               |
| <b>Equity</b>   |                    |                     |
| Capstone Therapeutics Corp. Stockholders' Equity  |                    |                     |
| Common Stock \$.0005 par value;<br>150,000,000 shares authorized; 54,385,411 shares outstanding<br>in 2019 and 2018 | 27                 | 27                  |
| Additional paid-in capital  | 190,490            | 190,483             |
| Accumulated deficit   | (193,277)          | (191,754)           |
| Total Capstone Therapeutics Corp. stockholders' equity (deficit)  | (2,760)            | (1,244)             |
| Noncontrolling interest   | -                  | -                   |
| <b>Total equity</b>   | <b>(2,760)</b>     | <b>(1,244)</b>      |
| <b>Total liabilities and equity</b>   | <b>\$ 703</b>      | <b>\$ 1,477</b>     |
| <i>See notes to unaudited condensed consolidated financial statements</i>   |                    |                     |

**CAPSTONE THERAPEUTICS CORP.**  
**CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS**  
*(in thousands, except per share data)*  
*(Unaudited)*

|   | Three months ended June 30, |                 | Six months ended June 30, |               |
|---|-----------------------------|-----------------|---------------------------|---------------|
|   | 2019                        | 2018            | 2019                      | 2018          |
| SUBLICENSE REVENUE  | \$ -                        | \$ 2,000        | \$ -                      | \$ 2,000      |
| OPERATING EXPENSES:   |                             |                 |                           |               |
| Sublicense transaction costs  | -                           | 254             | -                         | 254           |
| General and administrative  | 178                         | 84              | 366                       | 313           |
| Research and development  | 427                         | 322             | 1,028                     | 623           |
| Total operating expenses  | 605                         | 660             | 1,394                     | 1,190         |
| Income (loss) after operating expenses  | (605)                       | 1,340           | (1,394)                   | 810           |
| Interest and other income (expense), net  | (63)                        | (62)            | (126)                     | (122)         |
| Income (loss) from operations before taxes  | (668)                       | 1,278           | (1,520)                   | 688           |
| Income tax benefit (expense)  | -                           | -               | (3)                       | 3             |
| <b>NET INCOME (LOSS)</b>  | <b>(668)</b>                | <b>1,278</b>    | <b>(1,523)</b>            | <b>691</b>    |
| Less: Net Income (Loss) attributable to the noncontrolling interest                           | -                           | -               | -                         | -             |
| <b>Net Income (Loss) attributable to Capstone Therapeutics Corp. stockholders</b>             | <b>\$ (668)</b>             | <b>\$ 1,278</b> | <b>\$ (1,523)</b>         | <b>\$ 691</b> |
| Per Share Information:  |                             |                 |                           |               |
| Net Income (Loss), basic and diluted, attributable to Capstone Therapeutic Corp. stockholders | \$ (0.01)                   | \$ 0.02         | \$ (0.03)                 | \$ 0.01       |
| Basic and diluted shares outstanding  | 54,385                      | 54,385          | 54,385                    | 54,385        |
| <i>See notes to unaudited condensed consolidated financial statements</i>                     |                             |                 |                           |               |

**CAPSTONE THERAPEUTICS CORP.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
*(in thousands)*  
(Unaudited)

|   | <b>Six months ended June 30,</b> |                 |
|---|----------------------------------|-----------------|
|   | <b>2019</b>                      | <b>2018</b>     |
| <b>OPERATING ACTIVITIES</b>   |                                  |                 |
| Net loss  | \$ (1,523)                       | \$ 691          |
| Non cash items:   |                                  |                 |
| Amortization  | 39                               | 78              |
| Non-cash interest expense   | 119                              | 118             |
| Non-cash stock based interest expense                                     | 7                                | 6               |
| Change in other operating items:  |                                  |                 |
| Other current assets  | (274)                            | 87              |
| Accounts payable  | 552                              | 47              |
| Other accrued liabilities   | (6)                              | (11)            |
| Cash flows used in operating activities                                   | (1,086)                          | 1,016           |
| <b>INVESTING ACTIVITIES</b>   |                                  |                 |
| Cash flows provided by investing activities                               | -                                | -               |
| <b>FINANCING ACTIVITIES</b>   |                                  |                 |
| Secured Debt funding  | 50                               | -               |
| Cash flows provided by financing activities                               | 50                               | -               |
| <b>NET DECREASE IN CASH</b>   | <b>(1,036)</b>                   | <b>1,016</b>    |
| <b>CASH, BEGINNING OF PERIOD</b>  | <b>1,341</b>                     | <b>1,275</b>    |
| <b>CASH, END OF PERIOD</b>  | <b>\$ 305</b>                    | <b>\$ 2,291</b> |
| <i>See notes to unaudited condensed consolidated financial statements</i> |                                  |                 |

**CAPSTONE THERAPEUTICS CORP.**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**June 30, 2019**

**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). In 2012, we terminated the license for Chrysalin (targeting orthopedic indications). In 2014, we terminated the license for AZX100 (targeting dermal scar reduction). Capstone no longer has any rights to or interest in Chrysalin or AZX100.

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, other hyperlipidemic indications, and acute coronary syndrome/atherosclerosis regression. The initial AEM-28 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.

In early 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 of AEM-28, the JV has performed pre-clinical studies that have identified analogs of AEM-28, and new formulations, that have 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 2014).

The JV and the Company are exploring fundraising, partnering or licensing, to obtain additional funding to continue development activities and operations.

The JV and the Company do not have sufficient funding at this time to continue additional material development activities. 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 development activities.

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

#### 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. Apolipoprotein E (Apo E) is in a class of protein that occurs throughout the body. Apo E is essential for the normal metabolism of cholesterol and triglycerides. After a meal, the postprandial (or post-meal) lipid load is packaged in lipoproteins and secreted into the blood stream. Apo E targets cholesterol and triglyceride rich lipoproteins to specific receptors in the liver, decreasing the levels in the blood. Elevated plasma cholesterol and triglycerides are independent risk factors for atherosclerosis, the buildup of cholesterol rich lesions and plaques in the arteries. AEM-28 is a 28 amino acid mimetic of Apo E and AEM-28 analogs are also 28 amino acid mimetics of Apo E (with an aminohexanoic acid group and a phospholipid). 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, 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. Atherosclerosis is the major cause of cardiovascular disease, peripheral artery disease and cerebral artery disease, and can cause heart attack, loss of limbs and stroke. Defective lipid metabolism also plays an important role in the development of adult onset diabetes mellitus (Type 2 diabetes), and diabetics are particularly vulnerable to atherosclerosis, heart and peripheral artery diseases. Our joint venture has an Exclusive License Agreement with the University of Alabama at Birmingham Research Foundation for a broad domain of Apo E mimetic peptides, including AEM-28 and its analogs.

### **Company History**

Prior to November 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 (As described in Note B below) to develop 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).

**Basis of presentation, Going Concern, and Management’s Plans.** The accompanying financials 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.

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 to continue operations. Accordingly, the Company has significantly 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. As described in Note D below, the Company, on July 14, 2017, raised \$3,440,000, with net proceeds of approximately \$2,074,000, after paying off the Convertible Promissory Notes, and transaction costs of \$287,000. As discussed in Note B below, in August 2017, the Company used \$1,000,000 of the net proceeds to purchase 93,458 shares of LipimetiX Development, Inc.’s Series B-2 Preferred Stock. The additional funds, as well as a commitment of additional funding from the same investor group on an as needed basis of up to \$700,000, (Through an increase in its outstanding long-term debt. As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on March 19, 2019, on March 15, 2019 the Company entered into the Second Amendment to Securities Purchase, Loan and Security Agreement with Brookstone which provides additional funding for our operations up to a Maximum Amount of \$700,000.) alleviated the substantial doubt about the entity’s ability to continue as a going concern. However, additional funds will be required for the joint venture to reach its development goals and for the Company to continue its planned operations.

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 approximately 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, 2018. Information presented as of December 31, 2018 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 of America 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 the Company in the future, actual results may differ from these estimates and assumptions.

Our significant estimates include accounting for stock-based compensation.

### **Legal and Other Contingencies**

The Company is subject to legal proceedings and claims, as well as potential inquiries and actions by the Securities and Exchange Commission, that arise in the course of business. The Company records a liability when it is probable that a loss has been incurred and the amount is reasonably estimable. There is significant judgment required in both the probability determination and as to whether an exposure can be reasonably estimated. In the opinion of management, there was not at least a reasonable possibility the Company may have incurred a material loss with respect to loss contingencies. However, the outcome of legal proceedings and claims brought against the Company are subject to significant uncertainty.

Legal costs related to contingencies are expensed as incurred and were not material in either 2019 or 2018.

**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. As discussed in Note B below, in August 2017, the Company purchased 93,458 shares of LipimetiX Development, Inc.'s Series B-2 Preferred Stock for \$1,000,000. 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 allocated to the Series A preferred ownership. 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 and in 2016, \$946,000 in losses were allocated to the Series B-1 Preferred Stock ownership interests. As of March 31, 2018, losses incurred by the JV exceeded the capital accounts of the JV. The Company has a revolving loan agreement with the joint venture and advanced the joint venture funds for operations, with the net amount originally due December 31, 2016. As described in Note B below, the due date of the revolving loan has been extended to July 15, 2020, with early payment required upon certain additional funding of the joint venture by non-affiliated parties. 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.**

Cash consists of balances held in commercial bank accounts.

**Other Current Assets.** Other Current Assets at June 30, 2019 includes \$320,000 reimbursable under the Cooperation Agreement discussed below, and this amount will be used to satisfy certain obligations that are included in accounts payable or have been paid for by the Company as of June 30, 2019.

**Accounts Payable.** Accounts payable includes accrued and deferred officer compensation of \$185,000 and \$135,000 at June 30, 2019 and December 31, 2018, respectively, that is payable at various times and amounts through December 2020 and payable earlier on occurrence of certain transactions or approval by the Company's Board of Directors. Accounts payable at June 30, 2019 also includes a \$480,000 payable associated with the Cooperation Agreement discussed below.

**Stockholders' Equity.** During the first six months of 2019 and 2018 Additional paid-in capital increased by \$7,000 and \$6,000, respectively, due to the amortization of the cost of Warrants issued as part of the First Amendment to Securities Purchase, Loan and Security Agreement as described in Note D in these Condensed Consolidated Financial Statements. During the first six months of 2019 and 2018 Accumulated deficit increased (decreased) by \$1,523,000 and (\$691,000), respectively, due to the net loss (income) incurred in those first six months.

## **Revenue Recognition**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU 606") No. 2014-09 "Revenue from Contracts from Customers". Pursuant to ASC 606, revenue is recognized by the Company when a customer obtains control of promised goods or services. The amount of revenue that is recorded reflects the consideration that the Company expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

*Upfront License Fees:* If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company applies an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

## **Cooperation Agreement**

In May 2018 the Company's joint venture ("JV") entered into an agreement to cooperate with Anji Pharmaceuticals Inc. ("ANJI") (see Note E below) in the development of AEM-28 and its analogs. The JV entered into a License Agreement (the "Sub-License") with ANJI to sublicense, under its Exclusive License Agreement with the UAB Research Foundation, the use of the JV's AEM-28 and analogs intellectual property in the Territory of the People's Republic of China, Taiwan and Hong Kong (the "Territory"). As both parties intend to develop AEM-28 and its analogs, conducting independent development activities would result in both parties performing the same or similar pre-clinical work and clinical trial drug development. As such, the parties agreed to cooperate by the JV agreeing to perform certain preclinical work at its expense and for ANJI to cover the cost of clinical trial drug development. For efficiency and cost effectiveness the JV has agreed to manage the initial clinical trial drug development. Accordingly, the vendors performing the clinical trial drug development will bill the JV and ANJI will reimburse the JV. As provided for in ASC 606 and ASC 808 Cooperation Arrangements, the JV will net the reimbursements against the clinical trial drug development costs in Operating Expenses – Research & Development in the Consolidated Statements of Operations and the cash flow effect will be shown net in Operating Activities – Net Loss in the Consolidated Statements of Cash Flows in the Financial Statements included in this Current Report on Form 10-Q. ANJI cost and reimbursement activity under the Cooperation Agreement as of June 30, 2019 and December 31, 2018 totaled \$134,000 and \$52,000, respectively, and has been shown net. In the first six months of 2019 the Company charged costs totaling \$740,000 to research and development expense related to its activities under the Cooperation Agreement.

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-18 Collaborative Arrangements (Topic 808) - Clarifying the Interaction between Topic 808 and Topic 606. This ASU is effective for effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. As provided for in the ASU, the Company has elected to early adopt the ASU. The adoption of the ASU did not have a material effect on the Company's financial statements at June 30, 2019 or December 31, 2018.

## **Recent Accounting Pronouncements**

*Leases.* In February 2016 the FASB issued ASU 2016-02 *Leases (Topic 842)* and subsequently amended the guidance relating largely to transition considerations under the standard in January 2018 and July 2018. The objective of this update is to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those annual periods and is to be applied utilizing a modified retrospective approach. The new standard was adopted by the Company in the 1<sup>st</sup> quarter of 2019 and the adoption did not have a material effect on its financial position or operating results. The Company, at June 30, 2019, has recorded a right to use asset of \$20,000 in Other Current Assets and a lease liability of \$20,000 in Other Accrued Liabilities in the Consolidated Financial Statements included in this Quarterly Report on Form 10-Q. The adoption of the new standard is a non-monetary transaction and will have no effect on the Consolidated Statement of Cash Flows.

**Note B. JOINT VENTURE FOR DEVELOPMENT OF APO E MIMETIC PEPTIDE MOLECULE AEM-28 AND ANALOGS**

On August 3, 2012, we entered into a Contribution Agreement with LipimetiX, LLC to form a joint venture, LipimetiX Development, LLC (“JV”), to develop Apo E mimetic molecules, including AEM-28 and 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 Series A 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%. On August 11, 2017, the remaining \$3,500,000 (3,500,000 shares) of Series A preferred stock became convertible, at the Company’s option, into common stock, at the lower of the Series B Preferred Stock Conversion Price, as may be adjusted for certain events, or the price of the next LipimetiX Development, Inc. financing, exceeding \$1,000,000 on independently set valuation and terms. On August 11, 2017, the Company purchased 93,458 shares of LipimetiX Development, Inc.’s Series B-2 Preferred Stock for \$1,000,000 (LipimetiX Development, Inc. incurred \$15,000 in transaction costs as part of the Series B-2 Preferred Stock issuance, which was been shown as a reduction of Additional Paid in Capital on the Consolidated Statements of Changes in Equity and a cash flow provided by financing activities in the Consolidated Statements of Cash Flows at December 31, 2017). As discussed below, the JV Series B-1 and B-2 Preferred Stock issuances, because of the participating and conversion features of the preferred stock, effectively changes the Company’s ownership in the JV to 62.2%. With the Series B-1 and B-2 Preferred Stock on an as-converted basis, and the Company converting its Series A Preferred Stock to common stock, the Company’s ownership would change to 69.75%. The JV 2016 Equity Incentive Plan has 83,480 shares of the JV’s common stock available to grant, of which, at December 31, 2018, options to purchase JV common stock shares totaling 81,479 have been granted and are fully vested. All options were granted with an exercise price of \$1.07, vested 50% on the date of grant and monthly thereafter in equal amounts over a twenty-four-month period and are exercisable for ten years from the date of grant. If all stock available to grant in the JV 2016 Equity Incentive Plan were granted and exercised, and the Series B-1 Preferred Stock Warrants were exercised, the Company’s fully diluted ownership (on an as-converted basis) would be approximately 65.11%. On October 27, 2017 the Board granted Mr. Holliman an option to purchase 14,126 shares of the LipimetiX Development, Inc. Series B-2 Preferred Stock it currently owns, at an exercise price of \$10.70 per share, subject to adjustment and other terms consistent with the Series B-2 Preferred Stock. The option is exercisable for a five-year period from the date of grant. If exercised, this option would reduce the Company’s fully diluted ownership (on an as-converted basis including assumed exercise of other options and warrants) to approximately 64.31%.

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 currently composed of Dennis I. Goldberg, Ph.D. and Eric M. Morrel, Ph.D. 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 a 40% ownership interest in the JV at formation, 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.

As disclosed above, on August 11, 2017, the Company purchased 93,458 shares of LipimetiX Development, Inc.'s Series B-2 Preferred Stock for \$1,000,000.

Series B (B-1 and B-2) 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.

The Exclusive License Agreement assigned by LipimetiX, LLC to the JV on formation of the JV, 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 common stock ownership group, three 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 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 and an Accounting Services Agreement with the Company to manage JV accounting and administrative functions. The services related to these agreements have been completed. New Management and Accounting Services Agreements were entered into effective June 1, 2016. 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 August 2017 the Accounting Services Agreement monthly fee was increased to \$20,000 and will thereafter be accrued but not payable, until certain levels of joint venture funding are obtained from non-affiliated parties. At June 30, 2019, accounting fees of \$460,000 were earned but unpaid. In August 2017, a Management Fee of \$300,000 was approved by the

joint venture's Board of Directors with \$150,000 paid and charged to expense in the third quarter of 2017 and \$150,000 paid and expensed in the first quarter of 2018. In the 1<sup>st</sup> quarter of 2019 a Management Fee of \$50,000 was charged to expense and paid in the second quarter of 2019..

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

|                          |               |
|--------------------------|---------------|
| Patent license rights    | \$ 1,045      |
| Noncontrolling interests | <u>( 667)</u> |
| Cash paid at formation   | \$ 378        |

Patent license rights were recorded at their estimated fair value and were amortized on a straight-line basis over the key patent life of eighty months (fully amortized at June 30, 2019).

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. In the Company's consolidated financial statements, 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 and in 2016, \$946,000 of losses were allocated to the Series B-1 Preferred Stock ownership interests. As of December 31, 2018, losses incurred by the JV exceeded the capital accounts of the JV. The Company has a revolving loan agreement with the joint venture, with the loan due December 31, 2016. The due date of the revolving loan was extended to July 15, 2020, with early payment required upon certain additional funding of the joint venture by non-affiliated parties. Subsequent to June 30, 2017, interest due on the revolving loan will be accrued and payable only upon certain additional funding of the joint venture by non-affiliated parties. Until repayment, the outstanding revolving loan and interest balance is convertible, at the Company's option, into Series B Preferred Stock at the Series B-1 conversion price. 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 the unpaid loan and accrued interest balance. At June 30, 2019, the revolving loan agreement balance, including accrued interest subsequent to June 30, 2017 of \$160,000, was \$1,760,000.

The joint venture incurred net operating income (expenses), prior to the elimination of intercompany transactions, of (\$1,191,000) in 2019 and (\$10,789,000) for the period from August 3, 2012 (inception) to June 30, 2019, of which (\$1,191,000), and (\$9,177,000), 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 common stock noncontrolling interests represent an additional potential loss for the Company as the common stock 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 June 30, 2019, losses totaling \$667,000 have been allocated to the common stock 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 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 June 30, 2019, the Company would incur an additional loss of \$667,000 for the joint venture losses allocated to the common stock noncontrolling interests.

## **Note C AUSTRALIAN REFUNDABLE RESEARCH & DEVELOPMENT CREDIT**

In March 2014, LipimetiX Development LLC, (Now LipimetiX Development, Inc. - see Note B above) 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 43.5% of qualified expenditures. Subsequent to the end of its Australian tax years, Lipimetix Australia Pty Ltd submits claims for a refundable research and development tax credit. The expected refundable research and development tax credits for the six-month periods ended June 30, 2019 and 2018 were AUD\$0 and AUD\$4,000, respectively.

## **Note D SALE OF COMMON STOCK AND ISSUANCE OF SECURED DEBT**

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on July 17, 2017, on July 14, 2017, the Company entered into a Securities Purchase, Loan and Security Agreement (the "Agreement") with BP Peptides, LLC ("Brookstone"). The net proceeds have been used to fund our operations, infuse new capital into our joint venture, LipimetiX Development, Inc. ("JV") (As described in Note B above, in August 2017, the Company used \$1,000,000 of the net proceeds to purchase 93,458 shares of LipimetiX Development, Inc.'s Series B-2 Preferred Stock.), to continue its development activities, and pay off the Convertible Promissory Notes totaling \$1,000,000, plus \$79,000 in accrued interest.

Pursuant to the Agreement, Brookstone funded an aggregate of \$3,440,000, with net proceeds of approximately \$2,074,000, after paying off the Convertible Promissory Notes and transaction costs, of which \$1,012,500 was for the purchase of 13,500,000 newly issued shares of our Common Stock, and \$2,427,500 was in the form of a secured loan, due October 15, 2020. On July 14, 2017 Brookstone also purchased 5,041,197 shares of the Company's Common Stock directly from Biotechnology Value Fund affiliated entities, resulting in ownership of 18,541,197 shares of the Company's Common Stock, representing approximately 34.1% of outstanding shares of the Company's Common Stock at March 31, 2019.

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2018, on January 30, 2018, the Company entered into the First Amendment to Securities Purchase, Loan and Security Agreement (the "Amendment") with Brookstone. Interest on the Secured Debt was payable quarterly. The Amendment defers the payment of interest until the Secured Debt's maturity, October 15, 2020. In consideration for the deferral, the Company issued a Warrant to Brookstone to purchase up to 6,321,930 shares of the Company's Common Stock with an exercise price of \$.075 per share. The warrant expires October 15, 2025 and provides for quarterly vesting of shares in amounts approximately equal to the amount of quarterly interest payable that would have been payable under the Agreement, converted into shares at \$.75. At June 30, 2019, 3,405,151 shares are fully vested and exercisable.

The fair value of the Warrants was determined to be \$43,000. The fair value of the Warrants will be amortized over the deferral period, January 30, 2018 to October 15, 2020, on the straight-line basis, as additional interest expense. Amortization expenses totaled \$7,000 and \$6,000 in the first six months of 2019 and 2018, respectively, and is included in Interest and other expenses, net, in the Condensed Consolidated Statement of Operations.

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on March 19, 2019, on March 15, 2019 the Company entered into the Second Amendment to Securities Purchase, Loan and Security Agreement with Brookstone which provides additional funding for our operations up to a Maximum Amount of \$500,000. Any additional amounts advanced will be added to the current Loan and subject to the same terms and conditions. At Brookstone’s sole discretion, the Maximum Amount may be increased to an amount not to exceed \$700,000. The Company borrowed \$50,000 in March 2019 against the Maximum Amount of \$500,000. In August 2019 the lender agreed to increase the Maximum Amount to \$700,000.

Transaction costs of \$287,000 have been deferred and will be written off over the life of the secured loan, thirty-nine months from July 14, 2017 to October 20, 2020, on the straight-line basis. Additional transaction costs of \$12,000 were incurred with the Amendment and will be written off over the period of the date of the Amendment, January 30, 2018, to October 15, 2020. At June 30, 2019 transaction costs of \$179,000 has been amortized, and \$45,000 in the first six months of 2019 and 2018 has been included in the Condensed Consolidated Statements of Operations in Interest and Other Expenses. At June 30, 2019 and December 31, 2018, unamortized transaction costs of \$120,000 and \$165,000, respectively, have been netted against the outstanding Secured Debt balance on the Condensed Consolidated Balance Sheets. Interest payable on the Secured Debt is now due at loan maturity, October 15, 2020, and, at June 30, 2019 and December 31, 2018, accrued interest of \$287,000 and \$213,000, respectively, has been included in the Secured Debt balance on the Condensed Consolidated Balance Sheets. The interest on the secured debt of \$73,000, and \$72,000 in the first six months of 2019 and 2018, respectively, has been included in the Condensed Consolidated Statements of Operations in Interest and Other Expenses.

A summary of the Secured Debt activity is as follows (000’s):

|                   | June 30, 2019 | December 31, 2018 |
|-------------------|---------------|-------------------|
| Secured Debt      | \$ 2,477      | \$ 2,427          |
| Transaction costs | (299)         | (299)             |
|                   | \$ 2,178      | \$ 2,128          |
| Amortization      | 179           | 134               |
|                   | \$ 2,357      | \$ 2,262          |
| Accrued interest  | 287           | 213               |
|                   | \$ 2,644      | \$ 2,475          |

The secured loan bears interest at 6% per annum, with interest payable quarterly (now due at loan maturity) and is secured by a security interest in all of our assets. As part of the Agreement, the Company and Brookstone entered into a Registration Rights Agreement granting Brookstone certain demand and piggyback registration rights. A provision in the Agreement entered into with Brookstone also requires the Company to nominate two candidates for a director position that have been recommended by Brookstone as long as Brookstone beneficially owns over 20% of the Company’s outstanding common stock and to nominate one candidate for a director position that has been recommended by Brookstone as long as Brookstone beneficially owns over 5% but less than 20% of the Company’s outstanding common stock.

On April 18, 2017, the Company and Computershare Trust Company, N.A., as Rights Agent (the “Rights Agent”) entered into Tax Benefit Preservation Plan Agreement (the “Plan”), dated as of April 18, 2017, between the Company and the Rights Agent, as described in the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 19, 2017. The Plan is intended to act as a

deterrent to any person (together with all affiliates and associates of such person) acquiring “beneficial ownership” (as defined in the Plan) of 4.99% or more of the outstanding shares of Common Stock without the approval of the Board (an “Acquiring Person”), in an effort to protect against a possible limitation on the Company’s ability to use its net operating loss carryforwards. The Board, in accordance with the Plan, granted an Exemption to Brookstone with respect to the share acquisition described above, and Brookstone’s acquisition of 5,041,197 shares of the Company’s Common Stock from Biotechnology Value Fund affiliated entities, making Brookstone an Exempt Person in respect of such transactions.

## **Note E LIPIMETIX DEVELOPMENT, INC. LICENSE AGREEMENT**

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2018, on May 2, 2018, our JV, LipimetiX Development, Inc., entered into a License Agreement (the “Sub-License”) with Anji Pharmaceuticals Inc. (“ANJI”) to sublicense, under its Exclusive License Agreement with the UAB Research Foundation, the use of the JV’s AEM-28 and analogs intellectual property in the Territory of the People’s Republic of China, Taiwan and Hong Kong (the “Territory”). The Sub-License calls for an initial payment of \$2,000,000, payment of a royalty on future Net Sales in the Territory and cash milestone payments based on future clinical/regulatory events. ANJI will perform all development activities allowed under the Sub-License in the Territory at its sole cost and expense. The JV recorded the receipt of the \$2,000,000 payment as revenue in the second quarter of 2018. Transaction costs related to the revenue totaled \$254,000 and consisted of a \$100,000 payment to the UAB Research Foundation, as required by the UAB Research Foundation Exclusive License Agreement, a \$100,000 advisory fee and \$54,000 in legal fees. As described in Note B above JV net losses exceed the JV capital accounts and all losses are being allocated to the Company. Revenue recorded for the \$2,000,000 payment reduced the amount of JV net losses previously allocated to the Company.

A copy of the UAB Research Foundation Exclusive License Agreement was attached as Exhibit 10.7 to the Company’s Quarterly Report on Form 10-Q for the period ending June 30, 2012 filed with Securities and Exchange Commission (“SEC”) on August 10, 2012. A copy of the First Amendment and Consent to Assignment of the Exclusive License Agreement was attached as Exhibit 10.3 to the Company’s Quarterly Report on Form 10-Q for the period ending June 30, 2012 filed with the SEC on August 10, 2012. The Second Amendment to the Exclusive License Agreement was attached as Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the SEC on January 30, 2015.

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

The following is management’s discussion of significant events in the three and six month periods ended June 30, 2019 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, 2018.

### **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). In 2012, we terminated the

license for Chrysalin (targeting orthopedic indications). In 2014, we terminated the license for AZX100 (targeting dermal scar reduction). Capstone no longer has any rights to or interest in Chrysalin or AZX100.

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, other hyperlipidemic indications, and acute coronary syndrome/atherosclerosis regression. The initial AEM-28 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.

In early 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 of AEM-28, the JV has performed pre-clinical studies that have identified analogs of AEM-28, and new formulations, that have 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 2014).

The JV and the Company are exploring fundraising, partnering or licensing, to obtain additional funding to continue development activities and operations.

The JV and the Company do not have sufficient funding at this time to continue additional material development activities. 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 development activities.

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

### 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. Apolipoprotein E (Apo E) is in a class of protein that occurs throughout the body. Apo E is essential for the normal metabolism of cholesterol and triglycerides. After a meal, the postprandial (or post-meal) lipid load is packaged in lipoproteins and secreted into the blood stream. Apo E targets cholesterol and triglyceride rich lipoproteins to specific receptors in the liver, decreasing the levels in the

blood. Elevated plasma cholesterol and triglycerides are independent risk factors for atherosclerosis, the buildup of cholesterol rich lesions and plaques in the arteries. AEM-28 is a 28 amino acid mimetic of Apo E and AEM-28 analogs are also 28 amino acid mimetics of Apo E (with an aminohexanoic acid group and a phospholipid). 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, 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. Atherosclerosis is the major cause of cardiovascular disease, peripheral artery disease and cerebral artery disease, and can cause heart attack, loss of limbs and stroke. Defective lipid metabolism also plays an important role in the development of adult onset diabetes mellitus (Type 2 diabetes), and diabetics are particularly vulnerable to atherosclerosis, heart and peripheral artery diseases. Our joint venture has an Exclusive License Agreement with the University of Alabama at Birmingham Research Foundation for a broad domain of Apo E mimetic peptides, including AEM-28 and 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 22, 2019, for the year ended December 31, 2018 are those that depend most heavily on these judgments and estimates. As of June 30, 2019, there have been no material changes to any of the critical accounting policies contained in our Annual Report for the year ended December 31, 2018.

### **Results of Operations Comparing Three-Month Period Ended June 30, 2019 to the Corresponding Period in 2018.**

*Sublicense Revenue:* As described in Note 12 to the Financial Statements included in the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 22, 2019, the JV entered into a License Agreement (the “Sub-License”) with Anji Pharmaceuticals Inc. (“ANJI”) to sublicense, under its Exclusive License Agreement with the UAB Research Foundation, the use of the JV’s AEM-28 and analogs intellectual property in the Territory of the People’s Republic of China, Taiwan and Hong Kong (the “Territory”). The Sub-License calls for an initial payment of \$2,000,000, payment of a royalty on future Net Sales in the Territory and cash milestone payments based on future clinical/regulatory events. ANJI will perform all development activities allowed under the Sub-License in the Territory at its sole cost and expense. The JV recorded the receipt of the \$2,000,000 payment as revenue in the second quarter of 2018. Transaction costs related to the sublicense totaled \$254,000 and were separately stated on the Consolidated Statement of Operations included in the Financial Statements included in the Annual Report on Form 10-K. There was no sublicense activity in the second quarter of 2019.

*General and Administrative (“G&A”) Expenses:* G&A expenses related to our ongoing operations were \$178,000 in the second quarter of 2019 compared to \$84,000 in the second quarter of 2018. Administration expenses were higher in the second quarter of 2019 than 2018 primarily due higher legal fees and other costs incurred in 2019 related to the Company’s Annual Meeting scheduled for August 22, 2019.

*Research and Development Expenses:* Research and development expenses were \$427,000 for the second quarter of 2019 compared to \$322,000 for the second quarter of 2018. Our research and development expenses increased due to the availability of funds from the ANJI sublicense income received in 2018, discussed above, but continues to reflect reduced spending as our development activities of AEM-28 and its analogs were limited, as we attempt to obtain additional funding.

*Interest and other income (expense), net:* Interest and other income (expense), net was (\$63,000) for 2019 compared to (\$62,000) for 2018. The expense is interest recorded on the Secured Debt and on the issuance of Warrants.

*Net Income (Loss) attributable to Capstone Therapeutics stockholders:* We incurred a net (loss) in the second quarter of 2019 of (\$.7) million compared to a net income of \$1.3 million in the second quarter of 2018. Net losses were comparable between periods after considering the above comments. Our operations and the development activities of AEM-28 and its analogs were limited, as we attempt to obtain additional funding.

### **Results of Operations Comparing Six-Month Period Ended June 30, 2019 to the Corresponding Period in 2018.**

*Sublicense Revenue:* As described in Note 12 to the Financial Statements included in the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 22, 2019, the JV entered into a License Agreement (the “Sub-License”) with Anji Pharmaceuticals Inc. (“ANJI”) to sublicense, under its Exclusive License Agreement with the UAB Research Foundation, the use of the JV’s AEM-28 and analogs intellectual property in the Territory of the People’s Republic of China, Taiwan and Hong Kong (the “Territory”). The Sub-License calls for an initial payment of \$2,000,000, payment of a royalty on future Net Sales in the Territory and cash milestone payments based on future clinical/regulatory events. ANJI will perform all development activities allowed under the Sub-License in the Territory at its sole cost and expense. The JV recorded the receipt of the \$2,000,000 payment as revenue in the second quarter of 2018. Transaction costs related to the sublicense totaled \$254,000 and were separately stated on the Consolidated Statement of Operations included in the Financial Statements included in the Annual Report on Form 10-K. There was no sublicense activity in the first six months of 2019.

*General and Administrative (“G&A”) Expenses:* G&A expenses related to our ongoing operations were \$366,000 in 2019 compared to \$313,000 in 2018. Administration expenses were higher in 2019 than 2018 primarily due higher legal fees in 2019.

*Research and Development Expenses:* Research and development expenses were \$1,028,000 for 2019 compared to \$623,000 for 2018. Our research and development expenses increased due to the availability of funds from the ANJI sublicense income received in 2018, discussed above, but continues to reflect reduced spending as our development activities of AEM-28 and its analogs were limited, as we attempt to obtain additional funding.

*Interest and other income (expense), net:* Interest and other income (expense), net was (\$126,000) for 2019 compared to (\$122,000) for 2018. The expense is interest recorded on the Secured Debt and on the issuance of Warrants.

*Net Income ( Loss) attributable to Capstone Therapeutics stockholders:* We incurred a net (loss) in 2019 of (\$1.5) million compared to a net income of \$.7 million in 2018. Net losses were comparable

between periods after considering the above comments. Our operations and the development activities of AEM-28 and its analogs were limited, 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 AEM-28 and its analogs. We contributed \$6.0 million and through December 31, 2018 we have loaned an additional \$1,760,000 (including deferred interest of \$160,000) 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. As described in Note D to the Financial Statements included in this Quarterly Report on Form 10-Q, the Company on July 14, 2017, raised \$3,440,000, with net proceeds of approximately \$2,074,000, after paying off the Convertible Promissory Notes, and transaction costs of \$287,000. As disclosed in Note E to the Financial Statements included in this Quarterly Report on Form 10-Q, on May 2, 2018, our JV entered into a License Agreement which resulted in the receipt of a \$2,000,000 nonrefundable payment (\$1,746,000 net of transaction costs). At June 30, 2019, we had cash of \$305,000, of which \$230,000 is held by our JV.

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on March 19, 2019, on March 15, 2019, the Company entered into the Second Amendment to Securities Purchase, Loan and Security Agreement with Brookstone. The 2<sup>nd</sup> Amendment provides for additional advances to the Company up to a Maximum Amount of \$500,000 to be used for Company operations. Advances made will be added to the secured debt and be subject to the terms and conditions of the Securities Purchase, Loan and Security Agreement. At Brookstone's sole discretion, the Maximum Amount of the advances may be increased to an amount not exceeding \$700,000. The Company borrowed \$50,000 in March 2019 against the Maximum Amount of \$500,000. In August 2019 the Lender agreed to increase the Maximum Amount to \$700,000.

We intend to continue limiting our internal operations to a virtual operating model in 2019; however, without additional funding, we will also limit the development activities of AEM-28 and its analogs. Lack of additional funding for development activities of AEM-28 and its analogs could would impair our ability to continue our current operations as planned.

Funding permitting, our planned operations in 2019 consist of continuing monitoring and participating in the management of the JV's 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 choose to extend the development of AEM-28 and its analogs. We cannot currently predict the amount of funds that will be required if we choose 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.

The Company has a secured loan of \$2,477,500, due October 15, 2020, from BP Peptides, LLC, an entity that at June 30, 2019 owns approximately 34.1% of the Company's common stock. Interest on the secured loan, at a rate of 6% per annum, is payable on the maturity date of the secured loan.

#### **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><br>John M. Holliman, III | Chairman and Chief Executive Officer<br>(Principal Executive Officer)                                | August 13, 2019 |
| <u>/s/ Les M. Taeger</u><br>Les M. Taeger                 | Senior Vice President and Chief<br>Financial Officer<br>(Principal Financial and Accounting Officer) | August 13, 2019 |

**CERTIFICATION**

I, John M. Holliman, III certify that:

1. I have reviewed this quarterly report on Form 10-Q of Capstone Therapeutics Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2019

By: /s/ John M. Holliman, III  
John M. Holliman, III  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATION

I, Les M. Taeger, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Capstone Therapeutics Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2019

By: /s/ Les M. Taeger

Les M. Taeger

Senior Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Capstone Therapeutics Corp. (the “Company”) on Form 10-Q for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of John M. Holliman, III, Executive Chairman and Principal Executive Officer of the Company, and Les M. Taeger, Senior Vice President and Chief Financial Officer, and Principal Financial and Accounting Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 13, 2019

/s/ John M. Holliman, III  
John M. Holliman, III  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

/s/ Les M. Taeger  
Les M. Taeger  
Senior Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

**Capstone Therapeutics Corp.**  
**(the “Company”)**  
**Exhibit Index to Quarterly Report on Form 10-Q**  
**For the Quarterly Period Ended June 30, 2019**

| 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  | <p>The following financial information from our Quarterly Report on Form 10-Q for the second quarter of fiscal year 2019, filed with the SEC on August 13, 2019 formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of June 30, 2019 and December 31, 2018, (ii) the Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2019 and 2018 (iii) the Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2019 and 2018, and (iv) Notes to Unaudited Condensed Consolidated Financial Statements.</p> <p>* Furnished herewith</p> |                               | X              |