

Capstone Therapeutics Corp.  
Form 10-K  
March 15, 2017

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

**FORM 10-K**

**[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2016

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

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

Commission file number: 0-21214

**CAPSTONE THERAPEUTICS CORP.**

*(Exact name of registrant as specified in its charter)*

Delaware  
(State or other jurisdiction of incorporation or organization)

86-0585310  
(IRS Employer Identification No.)

1275 West Washington Street, Suite 104, Tempe, Arizona 85281

*(Address of principal executive offices)*

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

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

Securities registered pursuant to Section 12(b) of the Act: None

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

Common Stock, par value \$.0005 per share

Preferred Share Purchase Rights

*(Title of Class)*

*(Name of each exchange on which registered)*

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
 Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.  Yes  No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this

Form 10-K. [ ]

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

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 “small 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 Act).

Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based upon the closing sale price of the registrant’s common stock as reported on the OTCQB on June 30, 2016 was approximately \$1,450,000. Shares of common stock held by each officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily conclusive.

**Documents incorporated by reference:** None

The number of outstanding shares of the registrant’s common stock on February 28, 2017, was 40,885,411.



CAPSTONE THERAPEUTICS CORP.

FORM 10-K ANNUAL REPORT

YEAR ENDED DECEMBER 31, 2016

**TABLE OF CONTENTS**

PAGE

<u>PART I</u>	4
<u>Item 1. Business</u>	4
<u>Item 1A. Risk Factors</u>	8
<u>Item 1B. Unresolved Staff Comments</u>	16
<u>Item 2. Properties</u>	16
<u>Item 3. Legal Proceedings</u>	16
<u>Item 4. Mine Safety Disclosures</u>	16
<u>PART II</u>	16
<u>Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	16
<u>Item 6. Selected Financial Data</u>	17
<u>Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 7A. Quantitative and Qualitative Disclosures about Market Risk</u>	24
<u>Item 8. Financial Statements and Supplementary Data</u>	24
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	24
<u>Item 9A. Controls and Procedures</u>	24
<u>Item 9B. Other Information</u>	25
<u>PART III</u>	26
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	26
<u>Item 11. Executive Compensation</u>	29
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	37

<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	<u>38</u>
<u>Item 14. Principal Accountant Fees and Services</u>	<u>38</u>
<u>PART IV</u>	<u>39</u>
<u>Item 15. Exhibits and Financial Statement Schedules</u>	<u>39</u>
<u>SIGNATURES</u>	<u>S-1</u>
<u>EXHIBIT INDEX</u>	<u>E-1</u>
<u>FINANCIAL STATEMENTS</u>	<u>F-1</u>

## PART I

### Item 1. Business

#### Overview 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, and/or an analog, as treatment for Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012) and other hyperlipidemic indications. The initial development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting reduction of cholesterol and triglycerides.

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

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



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

The JV and the Company do not have sufficient funding at this time to continue additional material development activities of AEM-28-14. 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-28-14 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. 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-28-14. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia-HoFH), or have hypercholesterolemia or hypertriglyceridemia, 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 a broad domain of Apo E mimetic peptides, including AEM-28 and 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, 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).

## Competition

The biopharmaceutical industry is characterized by intense competition and confidentiality. Cholesterol reduction therapy is one of the largest drug markets served by numerous approved medications and with numerous potential therapies in various stages of clinical development. Well known cardiovascular drug classes include the statins and PCSK9s. Our drug candidates, if approved, would not compete directly for the same patient population as statins and PCSK9s. In the orphan indication of HoFH, two drugs received FDA approval in 2013: Juxtapid from Aegerion and Kynamro from Sanofi/Genzyme. Juxtapid is currently being marketed and sold; Kynamro has been withdrawn from market. We may not be aware of the other biotechnology, pharmaceutical companies or public institutions that are developing pharmaceuticals or devices that may compete with our potential products. We also may not be aware of all the other competing products our known competitors are pursuing. In addition, these biotechnology companies and public institutions compete with us in recruiting for research personnel and subjects, which may affect our ability to complete our research studies. For additional discussion regarding the risks associated with our competition, see the risk factor ***“If our JV’s product candidates do not gain market acceptance or our competitors develop and market products that are more effective than our JV’s product candidates, our commercial opportunities will be reduced or eliminated”*** in the “Risk Factors” section in this Annual Report on Form 10K.

## Marketing and Sales

AEM-28-14 is not currently available for sale and we do not expect it to be available for sale for some time into the future, if ever. Thus, neither we nor our JV currently have any marketing or sales staff. External consultants and members of our staff provide some technical marketing support relating to the development of, and market need for, new potential products and additional therapeutic applications of products already under research.

## Research and Development

At December 31, 2016, we had two administrative employees and utilized consultants to perform various administrative, regulatory or research tasks. We have entered into consulting agreements with former employees in an effort to retain their availability to render services if and when needed.

Our research and development for 2016 and 2015 consisted primarily of work with or through our joint venture.

Through our joint venture, LipimetiX Development, Inc. (“JV”), we incurred expenses of \$1.0 million (\$.1 million when net of \$946,000 allocated to Series B-1 Preferred Stock owners, as described in Notes 1 and 9 included in the financial statements in this Annual Report on Form 10-K) and \$1.0 million relating to AEM-28-14 research efforts in 2016 and 2015, respectively. The JV has a development plan to pursue regulatory approval of AEM-28-14, as treatment for

Homozygous Familial Hypercholesterolemia (AEM-28 was granted Orphan Drug Designation by FDA in 2012) and other hyperlipidemic indications. The initial development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting cholesterol and lipid reduction.

In early 2014, JV received allowance from regulatory authorities in Australia permitting the JV to proceed with the planned clinical trials of AEM-28. 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 subjects 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 development activities with AEM-28, the JV performed limited pre-clinical studies that have identified an analog of AEM-28, referred to as AEM-28-14, and a new formulation, that has the potential of greater efficacy, higher human dose toleration and an extended composition of matter patent life (application filed in 2015). AEM-28-14 has become the JV's lead drug candidate for commercial development.

## Manufacturing

Currently, third parties certified under Good Manufacturing Practices manufacture AEM-28-14 for the JV in limited amounts for our clinical and pre-clinical studies. We use a primary manufacturer for the peptides used in our human clinical trials, but secondary manufacturers are available as needed. AEM-28-14 chemistry, manufacturing and control plan is currently based on an infusion formulation.

## Patents, Licenses and Proprietary Rights

The JV has an Exclusive License Agreement (the "Agreement") with the University of Alabama at Birmingham Research Foundation ("UABRF") covering a broad domain of Apo-E mimetic peptides including AEM-28 and certain analogs (included as Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012, filed with the Securities and Exchange Commission on August 10, 2012, and as amended effective December 15, 2014, included as Exhibit 10.1 to the Company's Current report on Form 8-K, filed with the Securities and Exchange Commission on January 30, 2015). The Agreement calls for payment of patent filing, maintenance and other related patent fees, as well as a royalty of 3% on Net Sales of Licensed Products during the Term of the Agreement. The Agreement terminates upon the expiration of all Valid Patent Claims within the Licensed Patents, currently estimated to be 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 payment 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 receive 5% of Non Royalty Income received.

## Insurance

Our business entails the risk of product liability claims. We currently have no product liability coverage. We are not currently engaged in clinical trials. We maintain a general liability insurance policy and an umbrella excess liability policy. There can be no assurance that liability claims will not exceed the coverage limit of such policies or that such insurance will continue to be available on commercially reasonable terms or at all. Product liability claims or claims arising from our clinical trials could have a material adverse effect on our business, financial condition and results of operations. We have not experienced any material liability claims to date resulting from our clinical trials.

Employees

As of December 31, 2016, we had two administrative employees in our operations and utilize consultants to perform a variety of administrative, regulatory or research tasks. We have entered into consulting agreements with various former key employees, but there is no assurance that these persons will be available in the future to the extent their services may be needed. As a research and development business, we believe that the success of our business will depend in part on our ability to identify, attract and retain qualified research personnel, both as employees and as consultants. We face competition from private companies and public institutions for qualified research personnel. None of our employees are represented by a union and we consider our relationship with our employees to be good.

## Additional Information about Capstone Therapeutics

We were incorporated as a Delaware corporation in July 1987 as IatroMed, Inc. We changed our name to OrthoLogic Corp. in July 1991. Effective October 1, 2008, OrthoLogic Corp. commenced doing business under the trade name of Capstone Therapeutics and we formally changed our name to Capstone Therapeutics Corp. on May 21, 2010. Our executive offices are located at 1275 West Washington Street, Suite 104, Tempe, Arizona 85281, and our telephone number is (602) 286-5520.

Our website address is [www.capstonethx.com](http://www.capstonethx.com). Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as well as any amendments to those reports, are available free of charge through our website as soon as reasonably practical after we file or furnish them to the U.S. Securities and Exchange Commission. Once at our website, go to the “Investors” section to locate these filings. Copies of the materials we file with the Securities and Exchange Commission can also be obtained free of charge from the Securities and Exchange Commission’s website at [www.sec.gov](http://www.sec.gov), or by contacting the Securities and Exchange Commission’s Public Reference Room at 100 F Street N.E., Washington, D.C. 20549 or by calling 1-800-SEC-0330.

We adopted a code of ethics that applies to all of our employees and has particular sections that apply only to our principal executive officer and senior financial officers. We posted the text of our code of ethics on our website in the “Investors” section of our website under “Corporate Governance”, “Code of Ethics.” In addition, we will promptly disclose on our website (1) the nature of any amendment to our code of ethics that applies to our principal executive officer and senior financial officers, and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such officer who is granted the waiver and the date of the waiver.

## Item 1A. Risk Factors

### Safe Harbor

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 Annual Report on Form 10-K 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 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;
- effect of non-compliance with the Securities and Exchange Commission’s (“SEC”) Rules and Regulations requiring our Annual Reports on Form 10-K for the years ended December 31, 2016 and 2015, to include an opinion of an Independent Public Accountant;
- the impact of the terms or conditions of agreements associated with funds obtained to fund operations;

- failure to obtain additional funds required to complete clinical trials and supporting research and production efforts
- necessary to obtain FDA or comparable foreign agencies approval for product candidates or secure development agreements with pharmaceutical manufacturers;
- the impact of using a virtual operating model;
- unfavorable results of product candidate development efforts;
- unfavorable results of pre-clinical or clinical testing;
- delays in obtaining, or failure to obtain FDA or comparable foreign agencies approvals;
- increased regulation by the FDA or comparable foreign agencies;
- the introduction of competitive products;
- impairment of license, patent or other proprietary rights;
- failure to successfully implement our drug development strategy for AEM-28-14;
- failure of the Company's common stock to continue to be listed on the OTCQB stock market; and
- the impact of present and future joint venture, collaborative or partnering agreements or the lack thereof;

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 Annual Report on Form 10-K 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.

## **Risks Related to Our Business and Industry**

***This Annual Report on Form 10-K has been filed with the SEC without an opinion of an independent public accountant, as required by current SEC rules and regulations, and as required to be listed on the OTCQB Markets.***

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

***The audit opinion from our independent accounting firm, Moss Adams, LLC, on our December 31, 2014 financial statements, included in our Annual Report on Form 10-K, filed with the SEC on March 16, 2015, includes an explanatory paragraph as to an uncertainty with respect to our ability to continue as a going concern.***

We had accumulated deficit balance of \$190 million as of December 31, 2016. Our net loss for the year ended December 31, 2016 was \$0.7 million. We currently have no pharmaceutical products being sold or ready for sale and do not expect to be able to introduce any pharmaceutical products or generate any revenue for at least several years. We expect to incur losses for at least the next several years. Our cash reserves are the primary source of our working capital. These circumstances raise substantial doubt about the Company's ability to continue as a going concern.

***We are a biopharmaceutical company with no revenue generating operations and high investment costs. Therefore, we will require additional funding to realize revenue from any of our JV's product candidates, and we may never realize any revenue if our JV's product candidates cannot be commercialized.***

Our current level of funds is not sufficient to support continued research to develop our JV's product candidates, and will not be sufficient to fund all the research expenses necessary to achieve commercialization of any of our JV's product candidates. We will require substantial additional capital, and/or a development partner, to complete the clinical trials and supporting research and production efforts necessary to obtain FDA or comparable foreign agencies' approval, if any, for our JV's product candidates. We may not receive any revenue from our JV's product candidates until we receive regulatory approval and begin commercialization of our JV's product candidates. We cannot predict whether, or when, that might occur.

***Our JV partners have significant rights as minority-interest stockholders of our JV. Although we effectively own 59.3% of the outstanding shares of our JV's common stock, the noncontrolling stockholders of the JV have the right to appoint a majority of the JV's board of directors.***

Pursuant to a Stockholders Agreement among all the stockholders of our JV, we have agreed that the board of directors of the JV will be composed of three individuals designated by the noncontrolling common stockholders, one individual designated by the Series B-1 Preferred Stock owners, and two individuals designated by us. Consequently, our designees do not control the JV's board of directors. If the JV fails to operate substantially in accordance with its annual budget, including the milestones specified therein, or fails to comply with its obligations under the Stockholders Agreement, we will thereafter have the right to appoint a majority of the members of the JV's board of directors.

Under the Stockholders Agreement, the consent of stockholders acting by a majority in interest is required for a broad range of actions, including annual budgets and operational milestones. Because we are the majority stockholder, these consent rights protect our interests in the JV. However, there is a risk that these consent rights may be insufficient to protect our interests or may result in impasses with respect to the JV's management and operation, the resolution of which might result in actions, agreements or consequences that we might view as suboptimal. There is no assurance that the minority stockholders of the JV will share the same economic, business or legal interests or goals that we have for the JV's business.

***Our business is subject to stringent regulation, and if we do not obtain regulatory approval for our JV's product candidates, we will not be able to generate revenue.***

Our JV's research, development, pre-clinical and clinical trial activities and the manufacture and marketing of any products that it may successfully develop are subject to an extensive regulatory approval process by the FDA and other regulatory agencies in the United States and abroad. The process of obtaining required regulatory approvals for pharmaceutical products is lengthy, expensive and uncertain, and any such regulatory approvals may entail limitations on the indicated usage of a product, which may reduce the product's market potential.

None of our JV's product candidates have been approved for sale. In order to obtain FDA or comparable foreign agency approval to commercialize any product candidate, a New Drug Application (NDA) (or comparable foreign agency form) must be submitted demonstrating, among other things, that the product candidate is safe and effective for use in humans for each target indication. Our or our JV's regulatory submissions may be delayed, or we or our JV may cancel plans to make submissions for product candidates for many reasons, including unfavorable results from or delays in preclinical or clinical trials and lack of sufficient available funding.

If we experience delays in our JV's clinical trials, we will incur additional costs and our opportunities to monetize product candidates will be deferred. Delays could occur for many reasons, including the following:

- the FDA or other health regulatory authorities, or institutional review boards, do not approve a clinical study protocol or place a clinical study on hold;
- suitable patients do not enroll in a clinical study in sufficient numbers or at the expected rate, or data is adversely affected by trial conduct or patient drop out;
- patients experience serious adverse events, including adverse side effects of our JV's product candidates;
- patients in the placebo or untreated control group exhibit greater than expected improvements or fewer than expected adverse events;

third-party clinical investigators do not perform the clinical studies on the anticipated schedule or consistent with the clinical study protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;

service providers, collaborators or co-sponsors do not adequately perform their obligations in relation to the clinical study or cause the study to be delayed or terminated;

we experience difficulties in obtaining sufficient quantities of the particular product candidate or any other components needed for pre-clinical testing or clinical trials;

regulatory inspections of manufacturing facilities, which may, among other things, require us or a co-sponsor to undertake corrective action or suspend the clinical studies;

the interim results of the clinical study are inconclusive or negative;

the clinical study, although approved and completed, generates data that is not considered by the FDA or others to be sufficient to demonstrate safety and efficacy;

changes in governmental regulations or administrative actions affect the conduct of the clinical trial or the interpretation of its result;

there is a change in the focus of our JV's development efforts or a re-evaluation of its clinical development strategy;

and

we lack of sufficient funds to pay for development costs.

Consequently, we cannot assure that we or our JV will make submissions to the FDA or comparable foreign agencies in the timeframe that we have planned, or at all, or that our and our JV's submissions will be approved by the FDA or comparable foreign agencies. Even if regulatory clearance is obtained, post-market evaluation of our JV's future products, if required, could result in restrictions on a product's marketing or withdrawal of a product from the market as well as possible civil and criminal sanctions.

***If our JV's product candidates do not gain market acceptance or our competitors develop and market products that are more effective than our JV's product candidates, our commercial opportunities will be reduced or eliminated.***

Even if our JV brings one or more products to market, there is no assurance that our JV will be able to successfully manufacture or market the products or that potential customers will buy them. Market acceptance will depend on our ability to demonstrate to physicians and patients the benefits of the future products in terms of safety, efficacy, and convenience, ease of administration and cost effectiveness, as well as on our JV's ability to continue to develop product candidates to respond to competitive and technological changes. In addition, we believe that market acceptance depends on the effectiveness of our marketing strategy, the pricing of our JV's future products and the reimbursement policies of government and third-party payors. Physicians may not prescribe our JV's future products, and patients may determine, for any reason, that our JV's product is not useful to them. Insurance companies and other third party payors may determine not to reimburse for the cost of the product.

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Several biotechnology and pharmaceutical companies, as well as academic laboratories, universities and other research institutions, are involved in research and/or product development for indications targeted for use by AEM-28-14. Most of our competitors have significantly greater research and development capabilities, experience in obtaining regulatory approvals and manufacturing, marketing, financial and managerial resources than we have.

Our competitors may succeed in developing products that are more effective than the ones we have under development or that render our proposed products or technologies noncompetitive or obsolete. In addition, certain of our competitors may achieve product commercialization before we do. If any of our competitors develops a product that is more effective than one that our JV is developing or plans to develop, or is able to obtain FDA or comparable foreign agencies' approval for commercialization before we do, we may not be able to achieve significant market acceptance for certain of our JV's products, which would have a material adverse effect on our JV's business.

For a summary of the competitive conditions relating to indications which we are currently considering for AEM-28 and its analogs, see “Competition” in this Annual Report on Form 10-K.

***If we cannot protect our joint venture’s AEM-28, AEM-28-14 and other patents, or our JV’s intellectual property generally, our JV’s ability to develop and commercialize its future products will be severely limited.***

Our success will depend in part on our joint venture’s ability to maintain and enforce patent protection for AEM-28, AEM-28-14 and each resulting product. Without patent protection, other companies could offer substantially identical products for sale without incurring the sizable discovery, development and licensing costs that our joint venture has incurred. Our JV’s ability to recover these expenditures and realize profits upon the sale of products would then be diminished.

AEM-28 is patented and patent applications for the AEM-28 analogs have been filed. There have been no successful challenges to the patents. However, if there were to be a challenge to these patents or any of the patents for product candidates, a court may determine that the patents are invalid or unenforceable. Even if the validity or enforceability of a patent is upheld by a court, a court may not prevent alleged infringement on the grounds that such activity is not covered by the patent claims. Any litigation to enforce our JV’s rights to use its or its licensors’ patents will be costly, time consuming and may distract management from other important tasks.

As is commonplace in the biotechnology and pharmaceutical industries, we employ, or engage as consultants, individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees or consultants are involved in research areas which are similar to those areas in which they were involved at their former employers, we may be subject to claims that such employees or consultants and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs and be a distraction to management and which may have a material adverse effect on us, even if we are successful in defending such claims.

We also rely on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, advisors and others. Nonetheless, we cannot assure that those agreements will provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. The risk that other parties may breach confidentiality agreements or that our trade secrets become known or independently discovered by competitors, could adversely affect us by enabling our competitors, who may have greater experience and financial resources, to copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies.

***Our success also depends on our JV’s ability to operate and commercialize products without infringing on the patents or proprietary rights of others.***



Third parties may claim that our JV or its licensors or suppliers are infringing their patents or are misappropriating their proprietary information. In the event of a successful claim against our JV or its licensors or suppliers for infringement of the patents or proprietary rights of others, our JV may be required to, among other things:

- pay substantial damages;
- stop using our JV's technologies;
- stop certain research and development efforts;
- develop non-infringing products or methods; and
- obtain one or more licenses from third parties.

A license required under any such patents or proprietary rights may not be available to our JV, or may not be available on acceptable terms. If our JV or its licensors or suppliers are sued for infringement, our JV could encounter substantial delays in, or be prohibited from, developing, manufacturing and commercializing its product candidates.

***Our reliance on third party clinical research organizations and other consultants could have a material effect on our JV's ability to conduct clinical trials and perform research and development. Product development costs to our JV and our JV's potential collaborators will increase, and our JV's business may be negatively impacted, if we experience delays in testing or approvals or if our JV needs to perform more or larger clinical trials than planned.***

To obtain regulatory approvals for new products, our JV must, among other things, initiate and successfully complete multiple clinical trials demonstrating to the satisfaction of the FDA or other regulatory authorities that our JV's product candidates are sufficiently safe and effective for a particular indication. We currently rely on third party clinical research organizations and other consultants to assist our JV in designing, administering and assessing the results of those trials and to perform research and development with respect to product candidates. In relying on those third parties, we are dependent upon them to timely and accurately perform their services. If third party organizations do not accurately collect and assess the trial data, our JV may discontinue development of viable product candidates or continue allocating resources to the development and marketing of product candidates that are not efficacious. Either outcome could result in significant financial harm to us.

***The loss of key management and scientific personnel may hinder our JV's ability to execute our business plan.***

As a small company our success depends on the continuing contributions of our management team and scientific consultants, and maintaining relationships with the network of medical and academic centers in the United States and centers that conduct our clinical trials. We have reduced our staff to two administrative employees and utilize consultants to perform a variety of administrative, regulatory or research tasks. We have entered into consulting agreements with various former key employees, but there is no assurance that these persons will be available in the future to the extent their services may be needed.

If we are not successful in retaining the services of former key employees it could materially adversely affect our business prospects, including our ability to explore partnering or development activities.

Our joint venture is managed under contract by Benu BioPharma Inc., which is comprised of two individuals (Dennis I. Goldberg, Ph.D., and Eric M. Morrel, Ph.D.). These individuals are minority stockholders in our JV.

Although there is a services contract with Benu BioPharma Inc., there is no direct agreement with these individuals for continued services and they are under no legal obligation to remain with Benu BioPharma Inc. We can give no

assurance that all or any of these individuals will continue to provide services to our joint venture. Should any of these individuals not continue to provide services to our joint venture, it could have a material adverse effect on our joint venture's ability or cost to develop AEM-28 and its analogs.

***Possible side effects of our JV's product candidates may be serious and life threatening. If one of our JV's product candidates reveals safety or fundamental efficacy issues in clinical trials, it could adversely impact the development path for our JV's other current product candidates for that peptide. We face an inherent risk of liability in the event that the use or misuse of our JV's future products results in personal injury or death.***

The occurrence of any unacceptable side effects during or after pre-clinical and clinical testing of our JV's product candidates, or the perception or possibility that our JV's product candidates cause or could cause such side effects, could delay or prevent approval of our JV's products and negatively impact its business. The use of our JV's product candidates in clinical trials may expose us and our JV to product liability claims, which could result in financial losses. Our clinical liability insurance coverage may not be sufficient to cover claims that may be made against us or our JV. In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us and our JV against losses. Any claims against us or our JV, regardless of their merit, could severely harm our financial condition, strain our management and other resources and adversely impact or eliminate the prospects for commercialization of the product which is the subject of any such claim.

***Healthcare reform and restrictions on reimbursements may limit our financial returns.***

Our ability to successfully commercialize our products may depend in part on the extent to which government health administration authorities, private health insurers and other third party payors will reimburse consumers for the cost of these products. Third party payors are increasingly challenging both the need for, and the price of, novel therapeutic drugs and uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third party reimbursement may not be available for our products to enable us to maintain price levels sufficient to realize an appropriate return on our investments in research and product development, which could restrict our ability to commercialize a particular product candidate.

**Risks Related to our Common Stock**

***The trading volume in our common stock is limited and our stock price is volatile, and therefore stockholders may not be able to sell their shares in desired amounts at the reported trading prices.***

The trading price for our common stock, which is traded in the over-the-counter market, has varied significantly in the past (from a high of \$9.32 to a low of \$0.04 during the period of January 1, 2004 through December 31, 2016) and may vary in the future due to a number of factors, including:

- announcement of the results of, or delays in, preclinical and clinical studies;
- the response by the SEC or the OTCQB Market to our decision not to engage an Independent Public Accountant to audit and express an opinion on our December 31, 2016 or 2015 Financial Statements;
- fluctuations in our operating results;
- developments in litigation to which we or a competitor is subject;
- announcements and timing of potential partnering, development collaboration or licensing transactions, merger, acquisitions, divestitures, capital raising activities or issuance of preferred stock;
- announcements of technological innovations or new products by us or our competitors;
- FDA and other regulatory actions;
- developments with respect to our or our competitors' patents or proprietary rights;
- public concern as to the safety of products developed by us or others; and
- changes in stock market analyst recommendations regarding us, other drug development companies or the pharmaceutical industry generally.

Our common stock is thinly traded, in part because over-the-counter trading volumes are generally significantly lower than those on stock exchanges. The trading volume for our common stock often varies widely from day to day. Because of the low trading volume, a relatively small amount of trading may greatly affect the trading price, the trading price may be subject to amplified decreases upon the occurrence of events affecting our business, and investors should not consider an investment in our common stock to be liquid. In addition, the broader stock market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating

performance of particular companies, and these broad market fluctuations may be even more pronounced for our thinly traded stock.

*Future share issuances may have dilutive and other material effects on our stockholders.*

We are authorized to issue 150,000,000 shares of common stock. As of December 31, 2016, there were 40,885,411 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options, warrants or additional investment rights. As of December 31, 2016, we had options outstanding to purchase approximately 3,611,706 shares of our common stock, the exercise price of which ranges between \$0.05 per share to \$1.53 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof. To the extent additional options are granted and exercised or additional stock is issued, the holders of our common stock will experience further dilution. At December 31, 2016, no shares remain available to grant under the 2015 Equity Incentive Plan.

In addition, in the event that any future financing or consideration for a future acquisition should be in the form of, be convertible into or exchangeable for, equity securities, investors will experience additional dilution.

***Certain provisions of our certificate of incorporation and bylaws will make it difficult for stockholders to change the composition of our board of directors (“Board”) and may discourage takeover attempts that some of our stockholders may consider beneficial.***

Certain provisions of our certificate of incorporation and bylaws may have the effect of delaying or preventing changes in control if our Board determines that such changes in control are not in the best interests of the Company and our stockholders. These provisions include, among other things, the following:

- a classified Board with three-year staggered terms;
- advance notice procedures for stockholder proposals to be considered at stockholders’ meetings;
- the ability of our Board to fill vacancies on the board;
- a prohibition against stockholders taking action by written consent;
- supermajority voting requirements for the stockholders to modify or amend our bylaws and specified provisions of our certificate of incorporation, and
- the ability of our Board to issue up to 2,000,000 shares of preferred stock without stockholder approval.

These provisions are not intended to prevent a takeover, but are intended to protect and maximize the value of our stockholders’ interests. While these provisions have the effect of encouraging persons seeking to acquire control of our company to negotiate with our Board, they could enable our Board to prevent a transaction that some, or a majority, of our stockholders might believe to be in their best interests and, in that case, may prevent or discourage attempts to remove and replace incumbent directors. In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which prohibits business combinations with interested stockholders. Interested stockholders do not include stockholders whose acquisition of our securities is pre-approved by our Board under Section 203.

***We may issue additional shares of preferred stock that have greater rights than our common stock and also have dilutive and anti-takeover effects.***

We have 2,000,000 shares of authorized preferred stock, the terms of which may be fixed by our Board. We presently have no outstanding shares of preferred stock. Our Board has the authority, without stockholder approval, to create and issue one or more series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. If we raise additional funds to continue development of AEM-28 and its analogs, or operations, we may issue preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

***We have not previously paid dividends on our common stock and we do not anticipate doing so in the foreseeable future.***

We have not in the past paid any dividends on our common stock and do not anticipate that we will pay any dividends on our common stock in the foreseeable future. Any future decision to pay a dividend on our common stock and the amount of any dividend paid, if permitted, will be made at the discretion of our Board.

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

On August 3, 2012, we entered into a joint venture with LipimetiX, LLC (now LipimetiX Development, Inc.) to develop the Apo E mimetic peptide AEM-28 and its analogs and we contributed \$6 million to the joint venture and at December 31, 2016 we have loaned an additional \$1.6 million to the joint venture. Our cash contribution to the joint venture represents a substantial proportion of our available cash.

The initial funded development plan was focused on the development of treatments using AEM-28 for Homozygous Familial Hypercholesterolemia and Refractory Hypercholesterolemia and extended through Phase 1a and 1b/2a clinical trials, which were completed in the fourth quarter of 2014. Our pre-clinical studies or clinical trials results may not be viewed by potential partners, licensees or acquirers, as successful, and we may not recover our investment. Even if our development efforts are viewed as successful, a liquidity event, if any, may be insufficient in size to recover our investment.

***Our joint venture is unable to continue additional development of AEM-28-14 without additional funding support and the Company does not have sufficient funds to continue either its operations or development funding, which may impair the ability of the joint venture or the Company to continue on a going concern basis.***

There is no assurance that we will have adequate funds available, or that we can obtain needed funding from third parties on terms acceptable to us, or at all. If the joint venture cannot complete its development work as planned due to a lack of funds, the value of our investment would be impaired, perhaps materially, as would be our ability to continue as a going concern.

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

We lease office space in a facility in Tempe, Arizona, which is an approximately 100,000 square foot facility designed and constructed for industrial purposes and is located in an industrial district. In July 2007, we entered into a five-year lease for 17,000 square feet of space in this Tempe facility, which became effective March 1, 2008. We amended this lease, effective March 1, 2013, to extend the lease for two additional years and reduce the square feet rented to 2,845. Additional amendments have extended this lease term to May 31, 2017. We believe the facility is well-maintained and adequate for use through the end of our lease term.

#### Item 3. Legal Proceedings



None

Item 4. Mine Safety Disclosures

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock commenced trading on Nasdaq on January 28, 1993 and was delisted by Nasdaq on July 21, 2011. Our common stock is currently traded on the OTCQB under the symbol "CAPS." The following table sets forth, for the fiscal periods indicated, the range of high and low sales prices of our common stock.

2016		2015	
High	Low	High	Low
\$0.13	\$0.07	\$0.24	\$0.17
\$0.10	\$0.06	\$0.25	\$0.13
\$0.08	\$0.04	\$0.24	\$0.15
\$0.09	\$0.04	\$0.17	\$0.10

As of February 28, 2017, 40,885,411 shares of our common stock were outstanding and held by approximately 748 stockholders of record.

### **Dividends**

We have never paid a cash dividend on our common stock. We do not intend to pay any cash dividends on our common stock in the foreseeable future.

### **Recent Sales of Unregistered Securities**

None.

### **Issuer Purchases of Equity Securities**

None.

### **Securities Authorized for Issuance under Equity Compensation Plan**

The information required by Item 201(d) of Regulations S-K is provided under Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, which is incorporated herein by reference.

Item 6. Selected Financial Data

N/ A

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

## OVERVIEW OF BUSINESS

### 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. (“CBI”), including its exclusive worldwide license for Chrysalin 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, LipimetiX Development, LLC (now LipimetiX Development, Inc.), (see Note 9 in Notes to Financial Statements included in this Annual Report on Form 10-K for more information) to develop Apo E mimetic peptide molecule AEM-28 and analogs.

Our development activities represent a single operating segment as they shared the same product development path and utilized the same Company resources. As a result, we determined that it is appropriate to reflect our operations as one reportable segment.

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 this Annual Report on Form 10-K, references to “we”, “our”, the “Company”, “Capstone Therapeutics”, “Capstone”, and “OrthoLogic” refer to Capstone Therapeutics Corp. References to our Bone Device Business refer to our former business line of bone growth stimulation and fracture fixation devices, including the OL1000 product line, SpinaLogic®, OrthoFrame® and OrthoFrame/Mayo. References to our joint venture, or the “JV”, refer to LipimetiX

Development, Inc. (previously LipimetiX, LLC).

### **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, and/or an analog, as treatment for Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012) and other hyperlipidemic indications. The initial development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting reduction of cholesterol and triglycerides.

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

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

The JV and the Company do not have sufficient funding at this time to continue additional material development activities of AEM-28-14. 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-28-14 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. 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-28-14. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia-HoFH), or have hypercholesterolemia or hypertriglyceridemia, 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 a broad domain of ApoE mimetic peptides, including AEM-28 and its analogs.

## Critical Accounting Policies and 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 best knowledge of current events and actions that may impact the Company in the future, actual results may differ from these estimates and assumptions. Our critical accounting policies are those that affect, or could affect our financial statements materially and involve a significant level of judgment by management.

*Income Taxes:* Accounting Standards Codification Topic 740 "Income Taxes" requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Changes in valuation allowances from period to period are included in the tax provision in the period of change. In determining whether a valuation allowance is required, we take into account all evidence with regard to the utilization of a deferred tax asset, including past earnings history, expected future earnings, the character and jurisdiction of such earnings, unsettled circumstances that, if unfavorably resolved, would adversely affect utilization of a deferred tax asset, carryback and carryforward periods, and tax strategies that could potentially enhance the likelihood of realization of a deferred asset. We have evaluated the available evidence about future taxable income and other possible sources of realization of deferred tax assets and have established a valuation allowance for all of our deferred tax assets of approximately \$57 million at December 31, 2016.

In March 2014, LipimetiX Development, LLC, now LipimetiX Development, Inc., (see Note 9 in the Financial Statements included in this Annual Report on Form 10-K for more information) 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 either 43.5% or 45% (depending on the tax period) 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 period ended June 30, 2014, Lipimetix Australia Pty Ltd received a refundable research and development tax credit of AUD\$227,000. For the tax periods ended December 31, 2014 and 2015 refundable research and development tax credits of AUD\$301,000 and AUD\$188,000, respectively, were received by LipimetiX Australia Pty Ltd. At December 31, 2016, a refundable research and development tax credit of AUD\$78,000 has been accrued, as it is more likely than not, that the recorded refundable research and development tax credit at December 31, 2016 will be approved and received.

*Patents:* Patent license rights were recorded at \$1,045,000, their estimated fair value on the date they were acquired, August 3, 2012. Their cost is amortized on a straight-line basis over the key patent life of eighty months. At December 31, 2016, accumulated amortization totaled \$692,000. If a change in conditions occurs, that indicates a material change in the future utility of the patent license rights, an evaluation will be performed to determine if impairment of the asset has occurred, and if so, the impairment will be recorded. Future utility of the patent license rights is dependent upon the Company's ability to raise additional funding to continue development of AEM-28-14 or to complete a sale, licensing or other transactions.



*Legal and Other Contingencies:* The Company is subject to legal proceedings and claims that arise in the course of business. The Company records a liability when it is probable that a loss has been incurred and the amount is reasonably estimable. There is significant judgment required in both the probability determination and as to whether an exposure can be reasonably estimated. In the opinion of management, there was not at least a reasonable possibility the Company may have incurred a material loss with respect to loss contingencies.

Losses previously allocated to the noncontrolling common stock interests represent an additional potential loss for the Company, as the noncontrolling common stock 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 additional losses associated with the joint venture. At December 31, 2016, losses totaling \$667,000 have been allocated to the noncontrolling common stock interests. The Company records a contingent loss 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 this loss contingency.

*Fair value measurements:* We determine the fair value measurements of our applicable assets and liabilities based on a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions.

*Stock based compensation:* Effective January 1, 2006, we adopted SFAS No. 123 (revised 2004), “Share-Based Payment”, now Accounting Standards Codification Topic 718 “Stock Compensation” (“ASC 718”). ASC 718 requires all share-based payments, including grants of stock options, restricted stock units and employee stock purchase rights, to be recognized in our financial statements based on their respective grant date fair values. Under this standard, the fair value of each employee stock option and employee stock purchase right is estimated on the date of grant using an option pricing model that meets certain requirements. We currently use the Black-Scholes option pricing model to estimate the fair value of our share-based payments. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. We use the historical volatility adjusted for future expectations. The expected life of the stock options is based on historical data and future expectations. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our stock options and stock purchase rights. The dividend yield assumption is based on our history and expectation of dividend payouts. The fair value of our restricted stock units is based on the fair market value of our common stock on the date of grant. Stock-based compensation expense recognized in our financial statements in 2006 and thereafter is based on awards that are ultimately expected to vest. We recognize compensation cost for an award with only service conditions that has a graded vesting schedule on a straight line basis over the requisite service period as if the award was, in-substance, a multiple award. However, the amount of compensation cost recognized at any date must at least equal the portion of grant-date fair value of the award that is vested at that date. For non-employees, this expense is recognized as the service is provided in accordance with ASC Topic 505-550 “Equity-Based Payments to Non-Employees.” The amount of stock-based compensation expense in 2006 and thereafter is reduced for estimated forfeitures. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We evaluate the assumptions used to value stock awards on a quarterly basis. If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past.

ASC 718 requires the benefits associated with tax deductions that are realized in excess of recognized compensation cost to be reported as a financing cash flow rather than as an operating cash flow as previously required. Subsequent to the adoption of ASC 718 on January 1, 2006, we have not recorded any excess tax benefit generated from option

exercises, due to our net operating loss carryforwards, which cause such excess to be unrealized.

*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 license and patent rights. Neither the Company nor the noncontrolling interests have an obligation to contribute additional funds to the joint venture or to assume any joint venture liabilities or to provide a guarantee of either joint venture performance or any joint venture liability. The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. Joint venture losses were recorded on the basis of common ownership equity interests until common ownership equity was reduced to \$0. Subsequent joint venture losses were being allocated to the Series A preferred ownership equity (100% Company). Subsequent to March 31, 2013, all joint venture losses had been allocated to the Company. On August 25, 2016 the JV raised \$1,012,000 (\$946,000 net of issuance costs) in a Series B-1 Preferred Stock and Warrant offering and in 2016 JV losses of \$946,000 were allocated to the Series B-1 Preferred Stock ownership interest. As of December 31, 2016, losses incurred by the JV exceed the capital accounts of the JV. The Company has a revolving loan agreement with the joint venture to advance the joint venture funds for operations in an amount not to exceed a net (net of expected tax credits or other funds obtained) of \$1,600,000, with the net amount due December 31, 2016. Losses incurred by the joint venture in excess of the capital accounts of the joint venture will be allocated to the Company to the extent of net outstanding advances.

## 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 did not elected early application. If additional funds are not obtained to continue the development of AEM-28-14, 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 balance of \$744,000 at December 31, 2016.

## Results of Operations Comparing Year Ended December 31, 2016 and 2015.

*General and Administrative (“G&A”) Expenses:* G&A expenses related to our ongoing operations were \$543,000 in 2016 compared to \$1,757,000 in 2015. Administration expenses decreased primarily due to a 50% reduction in salaries and consulting fee rates taken by all staff and consultants in March 2016, reduced professional fees and insurance costs from our decision to not engage an Independent Public Accountant to review our 2016 financial statements, and reduction of our insurance coverage, as part of our cost cutting efforts.

*Research and Development Expenses:* Research and development expenses were \$1,041,000 for 2016 compared to \$1,182,000 for 2015. Our research and development expenses in 2016 and 2015 included the operating expenses of LipimetiX Development, Inc., which totaled (net of intercompany transactions) \$1,021,000 for 2016, and \$904,000 for 2015. Our 2016 research and development expenses reflect spending of funds from the JV Series B-1 Preferred Stock and Warrant offering in August 2016. Our future development activities of AEM-28-14 will be limited, as we attempt to obtain additional funding.

*Interest and Other Expenses (Income), Net:* Interest and Other Expenses (Income), Net, increased from \$24,000 in 2015 to \$81,000 in 2016 due to interest accrued on the Convertible Promissory Notes Payable, as described in Note 10 to the financial statements included in this Annual Report on Form 10-K.

*Income Tax Benefit:* Income tax benefit in 2016 and 2015 consisted of a refundable Australian research and development tax credit, as described in Notes 4 and 7 to the financial statements included in this Annual Report on Form 10-K, related to our joint ventures’ Australian activities.

*Net Loss attributable to Capstone Therapeutics stockholders:* We incurred a net loss in 2016 of \$.6 million (net of \$.9 million allocated to the Series B-1 Preferred Stock ownership interest), compared to a net loss of \$2.8 million in 2015. Net loss includes operations of LipimetiX Development, Inc. Our future development activities of AEM-28 and its analogs, including AEM-28-14 will be limited, as we attempt to obtain additional funding.

## Results of Operations Comparing Year Ended December 31, 2015 and 2014.

*General and Administrative (“G&A”) Expenses:* G&A expenses related to our ongoing operations were \$1,757,000 in 2015 compared to \$1,453,000 in 2014. Administration expenses increased primarily due to costs related to the *qui tam* litigation, preparation and filing of a Registration Statement filed on Form S-1, and investor relations activities.

*Research and Development Expenses:* Research and development expenses were \$1,182,000 for 2015 compared to \$3,071,000 for 2014. Our research and development expenses in 2015 and 2014 included the operating expenses of LipimetiX Development, LLC, which totaled (net of intercompany transactions) \$904,000 for 2015, and \$2,354,000 for 2014. The joint ventures’ initial planned research activities were substantially completed as of December 31, 2014 and in 2015 limited work was performed.

*Interest and Other Expenses (Income), Net:* Interest and Other Expenses (Income), Net, decreased from \$43,000 in 2014 to \$24,000 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, with this income offset by a foreign exchange loss of \$120,000 related to our joint ventures’ Australian activities. In 2015 the foreign exchange loss was \$28,000.

*Income Tax Benefit:* Income tax benefit in 2015 and 2014 consisted of a refundable Australian research and development tax credit, as described in Notes 4 and 7 to the financial statements included in this Annual Report on Form 10-K, related to our joint ventures’ Australian clinical trial activities.

*Net Loss attributable to Capstone Therapeutics stockholders:* We incurred a net loss in 2015 of \$2.8 million compared to a net loss of \$4.2 million in 2014. Net loss includes operations of LipimetiX Development, LLC, which totaled (net of intercompany transactions) \$904,000 for 2015, and \$2,354,000 for 2014. The joint ventures’ initial planned research activities have been substantially completed as of December 31, 2014.

## 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 September 30, 2016 we have loaned an additional \$1,594,000 to the JV. The JV

raised \$1,012,000 (\$946,000 net of issuance costs) in the JV's Series B-1 Preferred Stock and Warrant offering in August 2016. At December 31, 2016, we had cash and cash equivalents of \$748,000, of which \$445,000 is held by our JV.

We intend to continue limiting our internal operations to a virtual operating model in 2017, however, without additional funding, we will not continue development of AEM-28-14 past completion of the limited projects currently under way. Lack of additional funding would impair our ability to continue our current operations and our ability to continue as a going concern.

Funding permitting, our planned operations in 2017 consist of continuing monitoring and participating in the management of the JV's AEM-28-14 development activities.

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

We will require additional funds if we chose to extend the development of AEM-28-14 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-28-14 and its analogs and to continue operations. In any event, to complete the clinical trials and supporting research and production efforts necessary to obtain FDA or comparable foreign agencies' approval for product candidates would require us to obtain additional capital. New sources of funds, including raising capital through the sales of our debt or equity securities, joint venture or other forms of joint development arrangements, sales of development rights, or licensing agreements, may not be available or may only be available on terms that would have a material adverse impact on our existing stockholders' interests.

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

#### **Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

Our investment portfolio is used to preserve our capital until it is required to fund our operations. We do not hold any derivative financial instruments in our investment portfolio. We maintain a non-trading investment portfolio of investment grade securities that limits the amount of non-U.S. government obligations credit exposure of any one issue, issuer or type of instrument. Due to the short duration and conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

#### **Item 8. Financial Statements and Supplementary Data**

Consolidated balance sheets as of December 31, 2016 and December 31, 2015 consolidated statements of operations, changes in equity and cash flows for each of the years in the two-year period ended December 31, 2016, together with the related notes are set forth on the "F" pages of this Form 10-K.

#### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

#### **Item 9A. Controls and Procedures**

##### **Conclusion Regarding the Effectiveness of 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-K. 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-K 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.



## **Management's Annual Report on Internal Control Over Financial Reporting**

The management of Capstone Therapeutics Corp is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a - 15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in the 1992 Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in the 1992 Internal Control - Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2016.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the Securities Exchange Commission that permit the Company to provide only management's report in this annual report.

**Management's Report on Changes in Internal Controls Over Financial Reporting**

There were no changes in our internal controls over financial reporting during the fiscal quarter ended December 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

**INFORMATION CONCERNING DIRECTORS**

On April 28, 2014, the Board of Directors increased the number of directors to four and Eric W. Fangmann was elected to fill the fourth Board seat at the Company's Annual Meeting held on June 12, 2014. On March 15, 2016, Mr. Fangmann resigned from the Board of Directors. On March 18, 2016, the Board of Directors decreased the number of Directors to three.

John M. Holliman, III

John M. Holliman III, 63, has served as Executive Chairman and Principal Executive Officer of the Company since April 2006 and has served as a director of the Company since September 1987 and as Chairman of the Board of Directors since August 1997. Since February 1993 he has been a general partner of entities which are the general partners of Valley Ventures, LP (formerly known as Arizona Growth Partners, LP), Valley Ventures II, LP, Valley Ventures III, LP, Valley Ventures III Annex, LP, all of which are venture capital funds that invest principally in life science companies.

John M. Holliman, III has over thirty years of business experience, including service on the boards of over forty companies, commercial lending experience with major financial institutions, and has been active in venture capital financing for over thirty years, concentrating in the medical/biotech industries. Mr. Holliman earned a BBA in Finance and a MBA from Southern Methodist University and a Master of International Management from the Thunderbird School of Global Management. During his career Mr. Holliman has gained substantial executive and board level experience in business, finance and operations. The Board believes the experience and knowledge of Mr. Holliman qualifies him to serve on our board.

Fredric J. Feldman, Ph.D. (1) (2) (3)

Fredric J. Feldman, Ph.D., 76, has been the President of FJF Associates, a consultant to health care venture capital and emerging companies, since February 1992 and has served as a director of the Company since 1991. From September 1995 to June 1996, he was the Chief Executive Officer of Biex, Inc., a women's healthcare company. He served as Chief Executive Officer of Oncogenetics, Inc., a cancer genetics reference laboratory, from 1992 to 1995. Between 1988 and 1992, Dr. Feldman was the President and Chief Executive Officer of Microgenics Corporation, a medical

diagnostics company.

Dr. Feldman received his Ph.D. in analytical chemistry from the University of Maryland. He has been a director of a number of public and private companies involved in the healthcare industry. The Board believes that Dr. Feldman's over 40 years of operating, scientific and business experience in the medical/biotech industry qualifies him for service on our board.

Elwood D. Howse, Jr. (1) (2) (3)

Elwood D. Howse, Jr., 77, has served as a director of the Company since September 1987. In 1982, Mr. Howse founded Cable, Howse and Ragen, investment banking and stock brokerage firm, subsequently known as Ragen MacKenzie. In 1977, Mr. Howse co-founded Cable & Howse Ventures, an early stage venture capital firm focused on technology. In 1976, he served as Vice President, Corporate Finance, for Foster & Marshall, a northwest stock brokerage firm. In 1974 he was the Chief Financial Officer of Seattle Stevedore Company and the Miller Produce Company. Mr. Howse has served as a corporate director and advisor to various public, private and non-profit enterprises. He served on the board of the National Venture Capital Association and is past President of the Stanford Business School Alumni Association. He currently serves on the boards of directors of Formotus, Inc., BeneSol Corporation, Stella Therapeutics, Inc. and not-for-profit, Junior Achievement of Washington. Mr. Howse holds a BS in Engineering from Stanford University and an MBA from Stanford Graduate School of Business.

The Board believes Mr. Howse's education and experience, particularly Mr. Howse's financial experience, which qualifies him to be designated as our financial expert on our Audit Committee, brings important financial and business experience to the board and qualifies him to serve on our board.

\*\*\*\*\*

- (1) Member of the Audit Committee
- (2) Member of the Compensation Committee
- (3) Member of the Corporate Governance/Nominating Committee

The Audit Committee, which is a separately-designated standing committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), consisted of Mr. Howse (Chairman), and Mr. Fangmann. On March 18, 2016, Dr. Feldman replaced Mr. Fangmann.

In particular, all Audit Committee members possess the required level of financial literacy, at least one member of the Audit Committee meets the current standard of requisite financial management expertise and the Board of Directors has determined that Elwood D. Howse, Jr., the Chairman of the Audit Committee, is an "audit committee financial expert" as defined in Item 407(d) of Regulation S-K of the Securities and Exchange Commission (the "SEC"). Additionally, Mr. Howse, Dr. Feldman and Mr. Fangmann are "independent directors", as defined in Nasdaq Listing Rule 5605(a)(2).

#### Executive Officers

The employment of Mr. Holliman and Dr. Steer was terminated effective October 31, 2011. They continue to perform many of their previous duties and responsibilities under consulting agreements.

The following table sets forth information regarding our executive officers and significant consultant:

<u>Name</u>	<u>Age</u>	<u>Title</u>
John M. Holliman, III	63	Executive Chairman and Principal Executive Officer
Randolph C. Steer, MD, Ph.D.	67	Consultant
Les M. Taeger	66	Senior Vice President, Chief Financial Officer and Principal Financial and Accounting Officer

John M. Holliman, III, became Executive Chairman and Principal Executive Officer of the Company on April 5, 2006 and has served as a director of the Company since September 1987 and as Chairman of the Board of Directors since

August 1997. Since February 1993 he has been a general partner of entities, which are the general partners of Valley Ventures, LP (formerly known as Arizona Growth Partners, LP), Valley Ventures II, LP, Valley Ventures III Annex, LP, all of which are venture capital funds that invest principally in life science companies.

Randolph C. Steer, MD, Ph.D. served as President of the Company from April 5, 2006 until October 31, 2011. Since then, Dr. Steer has provided scientific, regulatory and clinical consulting services to the Company. Dr. Steer has been an independent pharmaceutical, biotechnology and medical devices consultant since 1989, and has provided services to the Company since 2002. He has a broad scientific, medical and business background, including extensive experience in pre-clinical, clinical and regulatory affairs, having held key management positions in leading corporations and having served as an advisor to many companies in the United States and abroad. Dr. Steer has also advised numerous venture capital firms, investment banks and independent investors on the commercial development of drugs, biologics, diagnostics and medical devices. He has served as Associate Director of Medical Affairs at Marion Laboratories; Medical Director at Ciba Consumer Pharmaceuticals (Ciba-Geigy Corporation); Vice President, Senior Vice President and Member of the Executive Committee at Physicians World Communications Group; Chairman, President and Chief Executive Officer of Advanced Therapeutics Communications International, a global drug regulatory group, and Chairman and Chief Executive Officer of Vicus.com, Inc. He is a member of the Board of Trustees of the Mayo Clinic and the Board of Directors of Techne Corporation and Vital Therapies, and was a member of the Board of Directors of BioCryst Pharmaceuticals from 1994 to 2009. Dr. Steer received his MD degree from the Mayo Medical School and his Ph.D. from the University of Minnesota, where he also completed a residency and subspecialty training in clinical and chemical pathology. He is a Fellow of the American College of Clinical Pharmacology.

Les M. Taeger joined the Company as Senior Vice President and Chief Financial Officer on January 16, 2006. Mr. Taeger most recently served as Chief Financial Officer of CardioTech International, Inc. (currently AdvanSource Biomaterials Corporation) (“CardioTech”). CardioTech was a publicly-traded, medical device company that developed, manufactured and sold advanced products for the treatment of cardiovascular disease. From September 2000 to February 2004, when Mr. Taeger became Chief Financial Officer of CardioTech, Mr. Taeger served as Chief Financial Officer of Gish Biomedical, Inc. (“Gish”). Gish, which became a subsidiary of CardioTech pursuant to a merger transaction involving the companies in April 2003, specialized in the manufacture and sale of products used in open-heart surgery, vascular access and orthopedic surgery. Prior to his employment with CardioTech and Gish, Mr. Taeger was employed for over five years as Chief Financial Officer of Cartwright Electronics, Inc., a division of Meggitt, PLC. Mr. Taeger is a Certified Public Accountant, with a Bachelor’s degree in accounting.

#### Corporate Governance and Code of ethics

The Company’s code of ethics applies to all of its employees and has particular sections that apply only to its principal executive officer and senior financial officers. The Company has posted the text of its code of ethics on its website ([www.capstonethx.com](http://www.capstonethx.com)), under the “Investors” section under the link “Corporate Governance” “Code of Ethics”. In addition, the Company will promptly disclose on its website (1) the nature of any amendment to its code of ethics that applies to its principal executive officer and senior financial officers, and (2) the nature of any waiver, including an implicit waiver, from a provision of its code of ethics that is granted to one of these specified officers, the name of such officer who is granted the waiver and the date of the waiver.

The full Board of Directors addresses all matters regarding corporate governance (that is, the relationships of the Board, the stockholders and management in determining the direction and performance of the Company) and the procedural rules regarding the operation of the Board itself. As such, the Board reviews all proposals submitted by stockholders for action at the annual stockholders’ meeting.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Under the securities laws of the United States, the Company’s directors, its executive officers and any persons holding more than 10% of the Company’s Common Stock are required to report their initial ownership of the Company’s Common Stock and any subsequent changes in that ownership to the SEC. Specific due dates for these reports have been established, and the Company is required to disclose any failure to file by these dates. The Company believes that all of these filing requirements were satisfied during the year ended December 31, 2016.

In making these disclosures, the Company has relied solely on written representations of those persons it knows to be subject to the reporting requirements and copies of the reports that they have filed with the SEC.

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

A list of directors, executive officers and persons holding more than 10% of the Company's Common Stock is included in Item 12 under the caption "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in this Annual Report on Form 10-K.



## Item 11. Executive Compensation

## Compensation of Directors

The following table sets forth compensation awarded to, earned by or paid to the Company's directors during the last fiscal year. Mr. John Holliman, III is not included in this table and his compensation as a director is included in the Summary Compensation Table in the Executive Compensation section in this Annual Report on Form 10-K.

Name (a)	Fees Earned or Paid in Cash (\$)	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation (\$)	All Other Compensation (\$)	Total (\$)
		(c)	(d)		(e)	(f)	
Fredric J. Feldman, Ph.D.	7,000		5,000	-	-	-	12,000
Elwood D. Howse, Jr.	7,000		5,000	-	-	-	12,000
				-	-	-	

(1) Fair value of the grants at the date of the grants was determined using the Black-Scholes model as described in Note 5 to the Financial Statements included in this Annual Report on Form 10-K.

During the year ended December 31, 2016, the Company paid non-executive directors Board Fees of \$7,000. All directors are eligible for a grant of non-qualified stock options pursuant to the Company's 2005 Equity Incentive Plan. The Company granted to each director (Fangmann, Feldman, Holliman, Howse) non-qualified options to acquire 50,000 shares at an exercise price of \$0.10 per share on January 22, 2016 (fair value of \$4,000) and to Feldman and Howse, 40,000 shares at an exercise price of \$0.05 on November 10, 2016 (fair value \$1,000). These options vested immediately and were granted at the closing market price on the date of grant. All options have been granted with ten-year terms.

**Director Outstanding Equity Awards at Fiscal Year-End**

Name	Option Awards		Equity Incentive Plan	Options	Option
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options( #)Unexercisable	Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Exercise Price(\$)	Expiration Date
(a)	(b)	(c)	(d)	(e)	(f)
John M. Holliman, III	50,000			1.02	2/21/2018
	125,000			0.45	2/3/2019
	100,000			0.82	2/4/2020
	25,000			0.70	10/30/2018
	65,000			0.17	5/18/2022
	65,000			0.16	8/9/2022
	51,000			0.21	2/28/2023
	22,000			0.30	2/6/2014
	50,000			0.17	4/10/2015
	200,000			0.25	6/19/2025
	100,000			0.12	12/18/2025
Various directors:					
(1)(2)(3)	10,000			1.43	1/1/2017
(1)(2)(3)	10,000			1.35	1/1/2018
(1)(3)	25,000			0.70	10/30/2018
(1)(2)(3)	10,000			0.42	1/1/2019
(1)(2)(3)	10,000			0.72	1/1/2020
(1)(2)(3)	10,000			0.58	1/1/2021
(1)(2)(3)	10,000			0.26	1/1/2022
(1)(2)	35,000			0.17	5/18/2022
(1)(2)	42,500			0.16	8/9/2022
(1)(2)(3)	10,000			0.17	1/1/2023
(1)(3)	27,000			0.21	2/28/2023
(1)(2)(3)	10,000			0.26	1/1/2024
(1)(3)	12,000			0.30	2/6/2024
(1)(2)(3)	50,000			0.22	1/2/2025

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

(1)(3)	10,000	0.17	4/10/2025
(1)(2)(3)	50,000	0.25	6/19/2025
(1)(2)(3)	50,000	0.10	1/22/2026
(1)(3)	40,000	0.05	11/10/2026
Feldman, Fred (1)			
Holliman, John (2)			
Howse, Elwood (3)			

## **EXECUTIVE COMPENSATION**

### The Compensation Committee's Conclusion

The Compensation Committee, at its meeting held at the beginning of each fiscal year, formulates its recommendations regarding which compensation components will be adjusted for the upcoming year and what the performance bonus for the prior year will be.

### Board Approval

At the first Compensation Committee meeting of the year, the Compensation Committee reviews the Executive Chairman's and other executive officers' compensation and bonuses and presents its recommendations to the Board of Directors. The final total compensation package decision regarding the Executive Chairman is made by the Independent Directors in an Executive Session without the Executive Chairman or other members of management present, and the final decisions on other executives' total compensation packages are made by the full Board of Directors.

The following discussion is provided to facilitate stockholder understanding of the named executive officer compensation information included in this Annual Report on Form 10-K.

### **Officer and Key Consultant Compensation**

On October 13, 2011, the Company's Board of Directors (the "Board") adopted a plan to preserve cash during ongoing partnering efforts. Included in the actions taken was the termination of the employment of John M. Holliman, III, Executive Chairman and Randolph C. Steer, MD, Ph.D., President. These individuals have continued as consultants, rather than as employees, at consulting rates which would equate to approximately \$100,000 per year for Mr. Holliman and \$120,000 per year for Dr. Steer. As employees, their base compensation had been \$200,000 for Mr. Holliman and \$325,000 for Dr. Steer. Les M. Taeger, Chief Financial Officer and Senior Vice President has continued as an employee, but his base compensation was reduced from \$242,000 per year to \$120,000 (increased to \$135,000 for 2014 and decreased to \$67,500 on 3/1/2016) per year. All of these officers had also been eligible for an annual bonus based on individual and Company performance goals of up to 40% of their base compensation.

In 2016, to conserve the cash resources of the Company, Mr. Holliman received consulting cash compensation of \$47,000 and Dr. Steer received consulting cash compensation of \$4,000. In 2017, consulting cash compensation for

Mr. Holliman and Dr. Steer will be minimal, until additional funding is received by the Company. Additionally, all other employees and consultants cash compensation has been reduced in 2016, until additional funding is received by the Company.

### **Equity-Based Compensation**

We provide a certain level of cash compensation to each executive as both a short-term reward and to focus executive performance on short-term goals that are part of our long-term strategies. Additionally, we use a combination of stock option grants and common stock awards to generate a commitment to, and a long-term investment in, our Company. Grants and awards were determined based on the position and competitive factors, as well as substantial compensation reductions effective October 31, 2011.

### **Stock Option Grants**

In 2016, the Company granted no options to employees.

### **Common Stock Awards**

The Company did not grant any common stock awards in 2016.

**Fringe Benefits, Perquisites and Retirement Benefits.**

Our executive employee participates in group health, dental, life, and disability programs on the same basis as other employees. No perquisites are provided to executives that in aggregate exceed \$10,000 per year.

**Joint Venture Bonus Plan**

On August 9, 2012, our Board approved a performance-based incentive compensation plan (the “Plan”) for our executive and consultants who were primarily responsible for identifying the investment opportunity for the development of Apo E mimetic peptide AEM-28 and its analogs, a class of cardiovascular drugs targeting indications related to lowering blood cholesterol levels, completing the formation of the joint venture, LipimetiX Development, LLC ( now LipimetiX Development, Inc.) (the “JV”), and who will participate in the management of the JV.

The Plan provides for a bonus pool, shared 40% by Mr. Holliman, 40% by Dr. Steer and 20% by Mr. Taeger, of 2.5% of the cash or in-kind distributions from the JV to the Company after the Company has received the return of its initial \$6,000,000 investment. The individuals’ interest in the bonus pool vested 50% upon Board approval of the Plan (August 9, 2012) and vested 50% upon the presentation by the JV to its Members of quantitative/qualitative safety and efficacy results from all protocol-designated endpoints of the AEM-28 Phase 1b/2a clinical trial. The bonuses are fully vested at December 31, 2016; however, no amounts have been earned as of December 31, 2016.

## Summary Compensation Table

The following table sets forth, with respect to the years ended December 31, 2016, 2015 and 2014, compensation awarded to, earned by or paid to the Company's principal executive officer, principal financial officer and key consultant who were serving at the end of the last completed fiscal year (the "named executive officers").

Name	Year	Salary	Bonus	Stock Awards	Option Awards (1)	Non-Equity Incentive Plan Compensation	Non-qualified Deferred Compensation	All Other Compensation	Total
(a)	(b)	(\$) (c)	(\$) (d)	(\$) (e)	(\$) (f)	(\$) (g)	(\$) (h)	(\$) (i)	(\$) (j)
John M. Holliman, III Executive Chairman (Principal Executive Officer)	2016	\$47,000	-	-	\$4,000	-	-	\$4,000	\$55,000
	2015	\$54,000	-	-	\$67,000	-	-	\$16,000	\$137,000
	2014	\$100,000	-	-	\$7,000	-	-	31,000 (1)	\$138,000
Randolph C. Steer, MD, Ph.D., Consultant (former President)	2016	\$4,000	-	-	\$-	-	-	-	\$4,000
	2015	\$63,000	-	-	\$31,000	-	-	-	\$94,000
	2014	\$120,000	\$15,000	-	\$5,000	-	-	-	\$140,000
Les M. Taeger Chief Financial Officer (Principal Financial Officer)	2016	\$79,000	-	-	\$-	-	-	-	\$79,000
	2015	\$135,000	-	-	\$31,000	-	-	-	\$166,000
	2014	\$135,000	-	-	\$3,000	-	-	-	\$138,000

Mr. Holliman is a member of the Board of Directors and as a director, received compensation of \$4,000, \$16,000 and \$31,000, in cash, in 2016, 2015 and 2014, respectively. Mr. Holliman received total director's compensation (Board fees and option grants) of \$8,000, \$33,000 and \$38,000 in 2016, 2015 and 2014, respectively, as more fully described in the Compensation of Directors section of this Annual Report on Form 10-K. Mr. Holliman, received an option grant to purchase 50,000 shares of the Company's Common Stock on January 22, 2016 (fair value of \$4,000). Fair value of the grants at the date of the grants was determined using the Black-Scholes model as described, for 2016, in Note 5 to the Financial Statements included in this Annual Report on Form 10-K, for 2015, in Note 5 to our Annual Report on form 10-K filed with the Securities and Exchange Commission on March 30, 2016 and for 2014, in Note 5 to the Annual Report on form 10-K filed with the Securities and Exchange Commission on March 16, 2015.





## Option GRANTS / STOCK AWARDS

The following table sets forth information about stock option grants and stock awards during the last completed fiscal year to the executive officers named in the Summary Compensation Table.

**Grants of Plan-based Awards**

Name	Grant	All Other Stock Awards: Number of Shares of Stock or Units #	All Other Option Awards: Number of Securities Underlying Options #	Exercise or Base Price of Option Awards (\$/Share)	Grant Date Fair Value of Stock and Option Awards (\$)
(a)	(b)	(i)	(j)	(k)	(l)
John M. Holliman, III Executive Chairman	1/22/2016	-	50,000	\$ 0.10	4,000

(1) Fair value of the grants at the date of the grants was determined using the Black-Scholes model as described in Note 5 to the Financial Statements included in this Annual Report on Form 10-K.



**Outstanding Equity Awards at Fiscal Year END**

Name	Option Awards Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	
(a)	(b)	(c)	(e)	(f)	
John M. Holliman	10000	-	1.43	12/31/2017	
	10000	-	1.35	12/31/2018	
	50000	-	1.02	2/21/2018	
	25000	-	0.70	10/30/2018	
	10000	-	0.42	1/1/2019	
	125000	-	0.45	2/3/2019	
	10000	-	0.72	1/1/2020	
	100000	-	0.82	2/4/2020	
	10000	-	0.58	1/1/2021	
	10000	-	0.26	1/1/2022	
	65000	-	0.17	5/18/2022	
	65000	-	0.16	8/9/2022	
	10000	-	0.17	1/1/2023	
	51000	-	0.21	2/28/2023	
	10000	-	0.26	1/1/2024	
	22000	-	0.30	2/6/2024	
	50000	-	0.22	1/2/2025	
	50000	-	0.17	4/10/2025	
	250000	-	0.25	6/19/2025	
	100000	-	0.12	12/18/2025	
50000	-	0.10	1/22/2026		
Randolph C. Steer, MD, Ph.D.	50000	-	1.53	5/21/2017	
	50000	-	1.02	2/21/2018	
	75000	-	0.45	2/3/2019	
	50000	-	0.82	2/4/2020	
	50000	-	0.67	1/17/2021	
	65000	-	0.17	5/18/2022	
	65000	-	0.16	8/9/2022	
	51000	-	0.21	2/28/2023	
	10000	-	0.35	10/25/2023	
	22000	-	0.30	2/6/2024	
	50000	-	0.22	1/2/2025	
	40000	-	0.17	4/10/2025	
	100000	-	0.25	6/19/2025	
	Les M. Taeger	14706	-	1.02	2/21/2018
		50000	-	0.45	2/3/2019

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

35000	-	0.82	2/4/2020
25000	-	0.67	1/17/2021
45000	-	0.17	5/18/2022
45000	-	0.16	8/9/2022
29000	-	0.21	2/28/2023
10000	-	0.35	10/25/2023
15000	-	0.30	2/6/2024
50000	-	0.22	1/2/2025
40000	-	0.17	4/10/2025
100000	-	0.25	6/19/2025

Employment Contracts, Termination of Employment, and  
Change-in-Control Arrangements

Effective April 5, 2006, Mr. John M. Holliman, III, became Executive Chairman and Principal Executive Officer. On May 12, 2006, the Company entered into an agreement to compensate Mr. Holliman for his services as the Company's Executive Chairman and principal executive officer (the "Holliman Agreement").

Effective October 31, 2011, the employment of Mr. Holliman was terminated, which resulted in the acceleration of the vesting of the options to purchase shares of the Company's common stock held by Mr. Holliman, so that his options became exercisable, and payment of his severance benefit. Subsequent to October 31, 2011, Mr. Holliman has continued his role as Executive Chairman under a consulting agreement.

Effective April 5, 2006, Randolph C. Steer, MD, Ph.D., became President of the Company. Dr. Steer has performed services for the Company since 2002. On May 12, 2006, the Company also entered into an agreement with Randolph C. Steer, MD, Ph.D., to compensate Dr. Steer for his services as the Company's President and Chief Operating Officer (the "Steer Agreement").

Effective October 31, 2011, the employment of Dr. Steer was terminated which resulted in the acceleration of the vesting of the options to purchase shares of the Company's common stock held by Dr. Steer, so that his options became exercisable, and payment of his severance benefits. Subsequent to October 31, 2011, Dr. Steer has continued to provide services under a consulting agreement.

On January 10, 2006, the Company entered into an employment agreement with Les M. Taeger, dated as of January 10, 2006, effective as of January 16, 2006 (the "Taeger Employment Agreement"), pursuant to which Mr. Taeger serves as the Company's Senior Vice President / Chief Financial Officer. Under the Taeger Employment Agreement, Mr. Taeger may be terminated at any time, with or without cause, at the option of either the Company or Mr. Taeger. Mr. Taeger receives medical, dental and other fringe benefits generally granted to the Company's senior management.

Effective October 31, 2011, Mr. Taeger's annual base salary was reduced to \$120,000. Mr. Taeger's salary for 2015 was \$135,000 and on March 1, 2016, his salary was reduced to \$67,500.

In 2016, to conserve the cash resources of the Company, Mr. Holliman received consulting cash compensation of \$47,000 and Dr. Steer received consulting cash compensation of \$4,000. In 2017, consulting cash compensation for Mr. Holliman and Dr. Steer will continue to be at reduced levels, until additional funding is received by the Company. Additionally, all other employees and consultants cash compensation was reduced until additional funding is received

by the Company.

Under the Company's stock option plans, upon the occurrence of a merger in which the Company is not the surviving entity, a sale of substantially all of the assets of the Company, an acquisition by a third party of 100% of the Company's outstanding equity securities or a similar reorganization of the Company, 75% of all unvested options will vest, with the balance vesting equally over 12 months or according to the individual's vesting schedule, whichever is earlier. If the option holder loses his position with the Company as a result of the merger or sale, 100% of his options will immediately vest. Additionally, the Company's 2005 and 2015 Equity Incentive Plans provide that, upon a merger, consolidation or reorganization with another corporation in which the Company is not the surviving corporation, outstanding options shall be substituted on an equitable basis for options for appropriate shares of the surviving corporation, or optionees shall receive cash in exchange for cancellation of outstanding options.

At December 31, 2016, all options held by named executive officers were vested and had no intrinsic value and accelerated vesting clauses, if triggered at December 31, 2016, would have provided no additional compensation to the named executive officers.

## Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

**Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth information regarding the beneficial ownership of the Company's Common Stock at February 28, 2017 with respect to (i) each person known to the Company to own beneficially more than five percent of the outstanding shares of the Company's Common Stock, (ii) each director of the Company, (iii) each of the named executive officers and (iv) all directors and executive officers of the Company as a group. At February 28, 2017, there were 40,885,411 shares of the Company's Common Stock outstanding.

Beneficial Owner	Common Stock Beneficially Owned (1)	
	Number	Percent of Class
Fredric J. Feldman (2)	637,064	1.5
John M. Holliman, III (3)	1,585,170	3.8
Elwood D. Howse, Jr. (4)	634,203	1.5
Randolph C. Steer 65 (5)	723,298	1.7
Les M. Taeger (6)	553,280	1.3
BVF Group (7)	7,757,422	19.0
Lloyd Miller, III (8)	7,926,389	19.4
All directors and executive officers as a group (9)	4,133,015	9.4

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission ("SEC") and generally includes voting or investment power with respect to securities. In accordance with SEC rules, shares, which may be acquired upon exercise of stock options which are currently exercisable or which become (1) exercisable within 60 days of the date of the table, are deemed beneficially owned by the optionee. Except as indicated by footnote, and subject to community property laws where applicable, the persons or entities named in the table above have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them.

(2) Includes 411,500 shares Dr. Feldman has a right to acquire upon exercise of stock options. Voting and investment power shared with spouse.

(3) Includes 1,073,000 shares Mr. Holliman has a right to acquire upon exercise of stock options.

(4) Includes 411,500 shares Mr. Howse has a right to acquire upon exercise of stock options.

(5) Includes 678,000 shares Dr. Steer has a right to acquire upon exercise of stock options.

(6) Includes 458,706 shares Mr. Taeger has a right to acquire upon exercise of stock options.

(7)

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

BVF Group (Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P. BVF Investments, L.L.C., Investment 10, L.L.C., BVF Partners, L.P., BVF Inc.) is not a related party or otherwise affiliated with the Company, its directors or officers, and the principal business office of the Reporting Persons comprising the Group is located at 900 North Michigan Avenue, Suite 1100, Chicago, IL 60611.

Lloyd Miller, III, is not a related party or otherwise affiliated with the Company, its directors or officers, except that Lloyd Miller, III, recommended Eric W. Fangmann to be a Company Board of Director member and Eric W.

(8) Fangmann is the Chief Financial Officer of various business entities associated with Mr. Miller, and the principal business office of the Reporting Person is located at 222 Lakeview Avenue, Suite 160-365, West Palm Beach, Florida 33401

(9) Includes 3,032,706 shares directors and executive officers have a right to acquire upon exercise of stock options.

The address of each of the listed stockholders, unless noted otherwise, is in care of Capstone Therapeutics Corp., 1275 West Washington Street, Suite 104, Tempe, AZ 85281.



## EQUITY COMPENSATION PLANS

The following provides tabular disclosure of the number of securities to be issued upon the exercise of outstanding options, the weighted average exercise price of outstanding options, and the number of securities remaining available for future issuance under equity compensation plans as of December 31, 2016, aggregated into two categories - plans that have been approved by stockholders and plans that have not. See Note 5 to the Financial Statements included in this Annual Report on Form 10-K for additional information on our equity compensation plans.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity Compensation Plans approved by Security Holders	3,611,706	\$ 0.37	0
Equity Compensation Plans not approved by Security Holders	N/A	N/A	N/A
Total	3,611,706	\$ 0.37	0

## Item 13. Certain Relationships and Related Transactions, and Director Independence

In 2006 Mr. Holliman became Executive Chairman and Principal Executive Officer of the Company and is no longer an independent director under Nasdaq Listing Rule 5605(a)(2). Currently, the Board of Directors is composed of two outside directors who are independent directors under Nasdaq Listing Rule 5605(a)(2) and one director who is not an independent director under Nasdaq Listing Rule 5605(a)(2).

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The Board of Directors reviews transactions with related parties, but has no formal policies in place with respect to such reviews or the approval of such transactions. During 2016 there were no reported related party transactions with directors, executive officers or other related parties, which might have required disclosure under SEC rules or which were otherwise material to the Company.

The Company has entered into indemnity agreements with all of its directors and officers for the indemnification of and advancing of expenses to such persons to the fullest extent permitted by law.

Item 14. Principal Accountant Fees and Services

We have not engaged an independent public accountant to audit our fiscal years ended December 31, 2016 or 2015 financial statements.

Type of Fee	Amount
	2015
Audit Fee (1)	\$86,000
Audit-Related Fees (s)	\$22,000
Total Audit and Audit-Related Fees	\$108,000
Tax Fees (3)	\$-
All Other Fees (4)	\$-
Total Fees	\$108,000

- Audit fees include fees for services rendered in connection with the audits of the Company's financial statements, (1) and reviews of the financial statements included in the Company's quarterly reports on Form 10-Q during the applicable fiscal year.
- (2) Audit-related fees would include fees for services rendered for matters such as a business combination, sales of shares of the Company's common stock, and responses to accounting and reporting-related matters.
- (3) Tax fees would include fees for services rendered for tax compliance, preparation of original and amended tax returns, claims for refunds and other tax services.
- (4) Our principal accounting firms did not perform nor bill the Company for any other services during the fiscal years ended December 31, 2016 and 2015 that are appropriately classified as "All Other Fees."

The Audit Committee has concluded that the services provided by the principal accounting firm that were not related to the audit of the Company's financial statements were at all times compatible with maintaining that firm's independence.

Consistent with the rules of the Securities and Exchange Commission regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation for, and overseeing the work of, the independent auditor. In recognition of this responsibility, the Audit Committee has included in its charter the responsibility to pre-approve "all auditing services and permitted non-auditing services proposed to be performed by the independent auditor, subject to the de minimis exceptions for non-audit services that were not recognized as non-audit services at the time of engagement and which are subsequently approved by the committee prior to completion of the audit." No fees were paid to the independent auditor pursuant to the "de minimis" exception to the foregoing pre-approval policy in 2016.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this report:

#### 1. Financial Statements.

The following financial statements of Capstone Therapeutics Corp. are presented in the "F" pages of this report:

Consolidated Balance Sheets - December 31, 2016 and 2015.

Consolidated Statements of Operations - Each of the years in the two-year period ended December 31, 2016.

Consolidated Statements of Changes in Equity - Each of the years in the two-year period ended December 31, 2016.

Consolidated Statements of Cash Flows - Each of the years in the two-year period ended December 31, 2016.

Notes to Consolidated Financial Statements.

2. Financial Statement Schedules have been omitted since they are not applicable.

3. All management contracts and compensatory plans and arrangements are specifically identified on the attached Exhibit Index.

(b) Exhibits

See the Exhibit Index following the signature page of this report, which Index is incorporated herein by reference.

(c) Financial Statements and Schedules - See Item 15(a)(1) and Item 15(a)(2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: March 15, 2017 By /s/ John M. Holliman, III  
John M. Holliman, III  
Principal Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ John M. Holliman, III</u> John M. Holliman, III	Executive Chairman (Principal Executive Officer) and Director	March 15, 2017
<u>/s/ Elwood D. Howse, Jr.</u> Elwood D. Howse, Jr.	Director	March 15, 2017
<u>/s/ Fredric J. Feldman</u> Fredric J. Feldman, Ph.D.	Director	March 15, 2017

/s/ Les M. Taeger

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

March 15,  
2017

Les M. Taeger

S-1

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

Capstone Therapeutics Corp. (“the Company”)

Exhibit Index to Annual Report on Form 10-K

For the Year Ended December 31, 2016

			Filed
			Or
			Furnished
			Herewith
<u>No.</u>	<u>Description</u>	<u>Incorporated by Reference To:</u>	
3.1	Amended and Restated Certificate of Designation of Series A Preferred Stock, executed June 24, 2014	Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission (“SEC”) on June 24, 2014	
3.2	Bylaws of the Company	Exhibit 3.4 to the Company’s Amendment No. 2 to Registration Statement on Form S-1 (No. 33-47569) filed with the SEC on January 25, 1993 (“January 1993 S-1”)	
3.3	Restated Certificate of Incorporation, as amended through June 24, 2014	Exhibit 3.1 to the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2014, filed with the SEC on August 14, 2014	
3.4	Second Amended and Restated Certificate of Incorporation as amended through June 22, 2016, including the Amended and Restated Certificate of Designation of Series A Preferred Stock	Exhibit 3.1 to the Company’s Registration Statement filed on Form S-1 with the SEC on June 26, 2015	
3.5	LipimetiX Development, Inc., Certificate of Incorporation and By Laws	Exhibit 3.3 to the Company’s Registration Statement filed on Form S-1 with the SEC on June 26, 2015	
10.1	Form of Indemnification Agreement(*)	Exhibit 10.16 to the Company’s January 1993 S-1	
10.2	Director Compensation Plan, effective June 10, 2005 (1)	Exhibit 10.2 to the Company’s Quarterly Report Form 10-Q for the quarterly period ended June 30, 2005, filed with the SEC on August 9, 2005	
10.3	Employment Agreement dated January 10, 2006 between the Company and Les M. Taeger (1)	Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the SEC on January 11, 2006 (the “January 11 8-K”)	

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

10.4	Intellectual Property, Confidentiality and Non-Competition Agreement between the Company and Les M. Taeger dated January 10, 2006 (1)	Exhibit 10.2 to the January 11 <sup>th</sup> 8-K
10.5	Amendment to Employment Agreement dated January 10, 2006 between OrthoLogic Corp. and Les Taeger (1)	Exhibit 10.3 to the Company's June 2006 10-Q
10.6	Contribution Agreement by and among LipimetiX, LLC, Capstone Therapeutics Corp., LipimetiX Development, LLC, The UAB Research Foundation, Dennis I. Goldberg, Ph.D. ("Goldberg"), Philip M. Friden, Ph.D., Eric Morrell, Ph.D., G. M. Anantharamaiah, Ph.D. and Palgunachari Mayakonda, Ph.D., Frederick Meyer, Ph.D., Michael Webb, and Jeffrey Elton, Ph.D., effective as of August 3, 2012.	Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012
10.7	Limited Liability Company Agreement of LipimetiX Development, LLC, by and among LipimetiX Development, LLC, Capstone Therapeutics Corp., and the other members and managers party thereto, effective as of August 3, 2012.	Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012
10.8	First Amendment and Consent to Assignment of Exclusive License Agreement by and among The UAB Research Foundation, LipimetiX, LLC and LipimetiX Development, LLC, dated as of August 3, 2012.	Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012
E-1		



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

- 10.9 Management Agreement by and among LipimetiX Development, LLC, Benu BioPharma, Inc., Dennis I. Goldberg, Ph.D., Phillip M. Friden, Ph.D., and Eric M. Morrel, Ph.D., effective as of August 3, 2012. Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012
- Accounting Services Agreement by and among LipimetiX Development, LLC and Capstone Therapeutics Corp., effective as of August 3, 2012 Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012
- 10.10 Escrow Agreement by and among Capstone Therapeutics Corp., LipimetiX Development, LLC dated as of August 3, 2012 Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012
- 10.18 Exclusive License Agreement between the UAB Research Foundation and LipimetiX LLC dated August 26, 2011 Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012
- 10.12 Second Amendment to Exclusive License Agreement between the UAB Research Foundation and LipimetiX, LLC, last signed on January 26, 2015 Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 30, 2015
- 10.13 Capstone Therapeutics Corp. Joint Venture Bonus Plan Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2012, filed with the SEC on November 8, 2012
- 10.14 Accounting Services Agreement Amendment #1, dated August 23, 2013 Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2013, filed with the SEC on November 12, 2013
- 10.15 Form of Incentive Stock Option Grant Letters under the 2015 Equity Incentive Plan \*\* Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on June 22, 2015
- 10.16 Form of Director Non-Qualified Stock Option Grant Letters under the 2015 Equity Incentive Plan \*\* Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on June 22, 2015
- 10.17 Form of Non-Qualified Stock Option Grant Letters under the 2015 Equity Incentive Plan \*\* Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on June 22, 2015
- 10.18 2015 Equity Incentive Plan Appendix A to the Company's Definitive Proxy Statement filed on Schedule 14A with the SEC on May 8, 2015
- 10.19 LipimetiX Development Certificate of Conversion from a Delaware Limited Liability Company to a Delaware Corporation Effective as of June 25, 2015 Exhibit 2.1 to the Company's Registration Statement filed on Form S-1 with the SEC on June 26, 2015
- 10.20 LipimetiX Development Plan of Conversion Effective as of June 25, 2015 Exhibit 2.2 to the Company's Registration Statement filed on Form S-1 with the SEC on June 26, 2015
- 10.21 Stockholders Agreement dated June 23, 2015 by and among LipimetiX Development, Inc. and Stockholders Exhibit 10.31 to the Company's Registration Statement filed on Form S-1 with the SEC on

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

- June 26, 2015
- 10.23 Securities Purchase Agreement between Company and Lenders dated December 11, 2015 Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 15, 2015
- 10.24 Convertible Promissory Note between the Company and Biotechnology Value Fund, L.P., dated December 11, 2015 Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on December 15, 2015
- 10.25 Convertible Promissory Note between the Company and Biotechnology Value Fund II, L.P., dated December 11, 2015 Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on December 15, 2015
- 10.26 Convertible Promissory Note between the Company and Biotechnology Value Trading Fund OS, L.P., dated December 11, 2015 Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on December 15, 2015

E-2

10.27	Convertible Promissory Note between the Company and Investment 10, LLC., dated December 11, 2015	Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the SEC on December 15, 2015	
10.28	Convertible Promissory Note between the Company and MSI BVF SPV, LLC., dated December 11, 2015	Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the SEC on December 15, 2015	
10.29	LipimetiX Development, Inc, Series B Preferred Stock and Warrant Purchase Agreement effective August 25, 2016	Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 26, 2016	
10.30	Series B Preferred Stock and Warrant Purchase Agreement – Exhibit B – Form of Warrants	Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on August 26, 2016	
10.31	Series B Preferred Stock and Warrant Purchase Agreement – Exhibit C – Form of Amended and Restated Certificate of Incorporation of LipimetiX Development, Inc.	Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on August 26, 2016	
10.32	Series B Preferred Stock and Warrant Purchase Agreement – Exhibit F – Form of Registration Rights Agreement	Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on August 26, 2016	
10.33	Series B Preferred Stock and Warrant Purchase Agreement – Exhibit G – Form of Amended and Restated Stockholders Agreement among LipimetiX Development, Inc. and The Stockholders Named Herein	Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the SEC on August 26, 2016	
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a -14(a) of the Securities Exchange Act of 1934, as amended		X
31.2	Certification of Principal Financial and Accounting Officer Pursuant to Rule 13a -14(a) of the Securities Exchange Act of 1934, as amended		
32.1	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350****		X
101	The following financial information from our Annual Report on Form 10-K for the fiscal year 2016, filed with the SEC on March 15, 2017 formatted in Extensible		X

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

Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as December 31, 2016 and 2015, (ii) the Consolidated Statements of Operations for the two years ended 2016 and 2015 (iii) the Consolidated Statements of Cash Flows for the two years ended December 31, 2016 and 2015 and (iv) Notes to Consolidated Financial Statements. \*\*\*

- (1) Management contract or compensatory plan or arrangement.

E-3

\* Capstone Therapeutics Corp. has entered into separate indemnification agreements with each of its current directors and executive officers that differ only in party names and dates. Pursuant to the instructions accompanying Item 601 of Regulation S-K, Capstone has filed the form of such indemnification agreement.

\*\* Capstone Therapeutics from time to time issues stock options to its employees, officers and directors pursuant to its 2015 Stock Option Plan, as amended. The incentive stock option grant letters and non-qualified stock option grant letters that evidence these issuances differ only in such terms as the identity of the recipient, the grant date, the number of securities covered by the award, the price(s) at which the recipient may acquire the securities and the vesting schedule. Pursuant to the instructions accompanying Item 601 of Regulation S-K, Capstone has filed the form of such incentive stock option grant letter and non-qualified stock option grant letter.

\*\*\* Furnished herewith.

**CAPSTONE THERAPEUTICS CORP.****CONSOLIDATED BALANCE SHEETS***(in thousands, except share and per share data)**(Unaudited)*

	December 31, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$748	\$1,011
Other current assets	81	247
Total current assets	829	1,258
Patent license rights, net	353	509
Furniture and equipment, net	-	-
Total assets	\$1,182	\$1,767
<b>LIABILITIES AND EQUITY</b>		
Current liabilities		
Accounts payable	\$249	\$254
Other accrued liabilities	55	7
Total current liabilities	304	261
Convertible Promissary Notes Payable	1,000	1,000
Equity		
Capstone Therapeutics Corp. Stockholders' Equity		
Common Stock\$.0005 par value; 150,000,000 shares authorized; 40,885,411 shares outstanding in 2016 and 2015	20	20
Additional paid-in capital	189,477	189,442
Accumulated deficit	(189,619)	(188,956)
Total Capstone Therapeutics Corp. stockholders' equity (deficit)	(122 )	506
Noncontrolling interest	-	-
Total equity	(122 )	506
Total liabilities and equity	\$1,182	\$1,767

See notes to unaudited consolidated financial statements

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

	2016	2015
<b>OPERATING EXPENSES</b>		
General and administrative	\$543	\$1,757
Research and development	1,041	1,182
Total operating expenses	1,584	2,939
Interest and other expenses (income), net	81	24
Loss from operations before taxes	1,665	2,963
Income tax benefit	(56 )	(192 )
Net Loss	1,609	2,771
Less: Net Loss attributable to the noncontrolling interest	(946 )	-
Net Loss attributable to Capstone Therapeutics Corp. stockholders	\$663	\$2,771
Per Share Information:		
Net loss, basic and diluted, attributable to Capstone Therapeutics Corp. stockholders	\$0.02	\$0.07
Basic and diluted shares outstanding	40,885	40,885

See notes to unaudited consolidated financial statements

**CAPSTONE THERAPEUTICS CORP.****CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY***(in thousands)**(Unaudited)*

	Capstone Therapeutics Corp. Stockholders' Equity					
	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Non controlling Interest	Total
Balance December 31, 2014	40,885	\$ 20	\$ 189,268	\$ (186,185 )	\$ -	\$3,103
Stock-based compensation cost	-	-	174	-	-	\$174
Net loss	-	-	-	(2,771 )	-	\$(2,771)
Balance December 31, 2015	40,885	20	189,442	(188,956 )	-	\$506
Series B-1 Preferred Stock					946	\$946
Stock-based compensation cost	-	-	35	-	-	\$35
Net loss	-	-	-	(663 )	(946 )	\$(1,609)
Balance December 31, 2016	40,885	\$ 20	\$ 189,477	\$ (189,619 )	\$ -	\$(122 )

See notes to unaudited consolidated financial statements



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

	Years Ended December 31,	
	2016	2015
<b>OPERATING ACTIVITIES</b>		
Net loss	\$(663 )	\$(2,771)
Non cash items:		
Depreciation and amortization	179	157
Non-cash stock-based compensation	35	174
Reduction in JV Losses recognized	(946 )	
Change in other operating items:		
Other current assets	143	308
Accounts payable	(5 )	130
Other accrued liabilities	48	(151 )
Cash flows used in operating activities	(1,209)	(2,153)
<b>INVESTING ACTIVITIES</b>		
Cash flows provided by investing activities	-	-
<b>FINANCING ACTIVITIES</b>		
Convertible Promissory Notes Payable	-	1,000
LipimetiX Development, Inc., Series B-1 Preferred Stock sale, net of issuance costs	946	-
Cash flows provided by financing activities	946	1,000
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(263 )</b>	<b>(1,153)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>1,011</b>	<b>2,164</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$748</b>	<b>\$1,011</b>

See notes to unaudited consolidated financial statements

CAPSTONE THERAPEUTICS CORP.

NOTES TO FINANCIAL STATEMENTS

## 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Overview 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, and/or an analog, as treatment for Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012) and other hyperlipidemic indications. The initial development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting reduction of cholesterol and triglycerides.

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

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

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

The JV and the Company do not have sufficient funding at this time to continue additional material development activities of AEM-28-14. 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-28-14 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. 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-28-14. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia-HoFH), or have hypercholesterolemia or hypertriglyceridemia, 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 a broad domain of Apo E mimetic peptides, including AEM-28 and 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 9 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.

F-6

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 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.

Management has determined that the Company will require additional capital above its current cash and working capital balances to further develop AEM-28-14 or 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. The audit opinion of our independent accounting firm on our December 31, 2014 financial statements, included in our Annual report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2016, included an explanatory paragraph as to the uncertainty with regards to our ability to raise funds to implement the future business strategy of the Company, raising substantial doubt about the Company’s ability to continue as a going concern. In August 2016, the Company’s joint venture raised net funds of \$946,000 in a Series B-1 Preferred Stock and Warrant offering. These funds allowed the joint venture to continue its development activities in 2016, but additional funds are required for both the joint venture and the Company to continue as a going concern.

These financial statements do not include any adjustments that might result from the outcome of this uncertainty of corporate strategy.

**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 income taxes, contingencies, accounting for stock-based compensation, accounting for the Australian refundable research and development tax credit, and accounting for the formation and consolidation of JV.

**Fair value measurements.** We determine the fair value measurements of our applicable assets and liabilities based on a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions.

F-7

**Cash and cash equivalents.** Cash and cash equivalents include money market accounts.

**Furniture and equipment.** Furniture and equipment are stated at cost. Depreciation is calculated on a straight-line basis over the estimated useful lives of the various assets, which range from three to seven years. Leasehold improvements are amortized over the life of the asset or the period of the respective lease using the straight-line method, whichever is the shortest.

**Research and development expenses.** Research and development represents costs incurred for research and development activities, including costs incurred to fund the pre-clinical and clinical testing of our product candidates. Research and development costs are generally expensed when incurred. Nonrefundable advance payments are capitalized and recorded as expense when the respective product or service is delivered.

**Accrued Clinical.** Accrued clinical represents the liability recorded for the costs incurred for our human clinical trials. Total patient costs are based on the specified clinical trial protocol, recognized over the period of time service is provided to the subject. We had no active clinical trials at December 31, 2016 or December 31, 2015.

**Stock-based compensation.** We account for share-based compensation arrangements in accordance with ASC Topic 718 “Compensation - Stock Compensation” (“ASC 718”). ASC 718 requires all share-based payments, including grants of stock options, restricted stock units and employee stock purchase rights, to be recognized in our financial statements based on their respective grant date fair values. Under this standard, the fair value of each grant is estimated on the date of grant using a valuation model that meets certain requirements. We use the Black-Scholes option pricing model to estimate the fair value of our share-based payment awards. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model was affected by our stock price and a number of assumptions, including expected volatility, expected term, risk-free interest rate and an expected dividend yield. We used our historical volatility as adjusted for future expectations. The expected life of the stock options was based on historical data and future expectations of when the awards will be exercised. The risk-free interest rate assumption was based on observed interest rates with durations consistent with the expected terms of our stock options. The dividend yield assumption was based on our history and expectation of dividend payouts. The fair value of our restricted stock units was based on the fair market value of our common stock on the date of grant. We evaluated the assumptions used to value our share-based payment awards on a quarterly basis. For non-employees, expense was recognized as the service was provided and when performance was complete in accordance with ASC Topic 505 – 550 “Equity-Based Payments to Non-Employees.”

Effective January 1, 2006, stock-based compensation expense recognized in our financial statements has been based on awards that were ultimately expected to vest. We recognized compensation cost for an award with only service conditions that had a graded vesting schedule on a straight line basis over the requisite service period as if the award was, in-substance, a multiple award. However, the amount of compensation cost recognized at any date was at least equal to the portion of grant-date fair value of the award that was vested at that date. The amount of stock-based compensation expense is reduced for estimated forfeitures. Forfeitures were required to be estimated at the time of



grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates.

ASC 718 requires the benefits associated with tax deductions that are realized in excess of recognized compensation cost to be reported as a financing cash flow rather than as an operating cash flow as previously required. Subsequent to the adoption of ASC 718 on January 1, 2006, we have not recorded any excess tax benefit generated from option exercises, due to our net operating loss carryforwards, which cause such excess benefits to be unrealized.

F-8

The Company recorded stock-based compensation of \$35,000 in 2016 and \$174,000 in 2015, which increased the net loss. Loss per weighted average basic and diluted shares outstanding increased by less than \$0.01 per share in 2016 and \$0.01 per share in 2015 due to stock-based compensation.

**Loss per common share.** In determining loss per common share for a period, we use weighted average shares outstanding during the period for primary shares and we utilize the treasury stock method to calculate the weighted average shares outstanding during the period for diluted shares. Utilizing the treasury stock method for the year ended December 31, 2016, 1,000 shares were determined to be outstanding and excluded from the calculation of loss per share because they were anti-dilutive. At December 31, 2016, options to purchase 3,611,706 shares of our common stock, at exercise prices ranging from \$0.05 to \$1.53 per share, were outstanding.

**Income Taxes.** Under ASC Topic 740 “Income Taxes” (“ASC 740”), income taxes are recorded based on current year amounts payable or refundable, as well as the consequences of events that give rise to deferred tax assets and liabilities. We base our estimate of current and deferred taxes on the tax laws and rates that are estimated to be in effect in the periods in which deferred tax liabilities or assets are expected to be settled or realized. Pursuant to ASC 740, we have determined that the deferred tax assets at December 31, 2016 and 2015 require a full valuation allowance given that it is not “more-likely-than-not” that the assets will be recovered.

We adopted the provisions of Financial Accounting Standards Board (“FASB”) Interpretation No. 48, “Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109” (now ASC 740) on January 1, 2007. ASC 740 clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC 740 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

Subsequent to adoption of ASC 740, each period we evaluate the tax years that remain open for assessment for federal and state tax purposes. At December 31, 2016, tax years 2012 through 2016 remain open.

We may, from time-to-time, be assessed interest or penalties by major tax jurisdictions, although any such assessments historically have been minimal and immaterial to our financial results. The Company recognizes accrued interest and penalties, if applicable, related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2016 and 2015, the Company did not recognize a material amount in interest and penalties.

**Patents.** Patent license rights were recorded at \$1,045,000, their estimated fair value on the date they were acquired, August 3, 2012. Their cost will be amortized on a straight-line basis over the key patent life of eighty months. At December 31, 2016, accumulated amortization totaled \$692,000. If a change in conditions occurs, that indicates a material change in the future utility of the patent license rights, an evaluation will be performed to determine if

impairment of the asset has occurred, and if so, the impairment will be recorded.

**Joint Venture Accounting.** The Company entered into a joint venture in which it has contributed \$6,000,000, and the noncontrolling interests have contributed certain patent license rights. Neither the Company nor the noncontrolling interests have an obligation to contribute additional funds to the joint venture or to assume any joint venture liabilities or to provide a guarantee of either joint venture performance or any joint venture liability. The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. Joint venture losses were recorded on the basis of common ownership equity interests until common ownership equity was reduced to \$0. Subsequent joint venture losses were allocated to the Series A and B-1 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 December 31,2016, losses incurred by the JV exceed the capital accounts of the JV. The Company has a revolving loan agreement with the joint venture to advance the joint venture funds for operations in an amount not to exceed a net (net of expected tax credits or other funds obtained) of \$1,600,000, with the net amount due December 31, 2016. Losses incurred by the joint venture in excess of the capital accounts of the joint venture will be allocated to the Company to the extent of net outstanding advances.

## Legal and Other Contingencies

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

Legal costs related to contingencies are expensed as incurred and were not material in either 2016 or 2015.

## 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.* 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 joint venture investment balance.

## 2. INVESTMENTS

At December 31, 2016 and December 31, 2015, investments were classified as held-to-maturity securities. As of December 31, 2016 and 2015, all investments were in a Money Market Fund with maturities less than 90 days, and are included in cash and cash equivalents.

## 3. FURNITURE AND EQUIPMENT

The components of furniture and equipment at December 31 are as follows (in thousands):

F-10

	December 31,	
	2016	2015
Machinery and Equipment	\$221	\$221
Furniture and fixtures	\$34	\$34
Leasehold Improvements	\$-	\$-
	\$255	\$255
Less accumulated depreciation and amortization	\$(255)	\$(255)
Total	\$-	\$-

Depreciation and leasehold improvement amortization expenses for the years ended December 31, 2015 and 2014 were \$0 and \$0, respectively.

#### 4. INCOME TAXES

The components of deferred income taxes at December 31 are as follows (in thousands):

	December 31,	
	2016	2015
Accruals and reserves	\$1	\$1
Valuation allowance	\$(1 )	\$(1 )
Total current	\$-	\$-
NOL, AMT and general business credit carryforwards	\$56,602	\$57,096
Other	\$102	\$262
Valuation allowance	\$(56,704)	\$(57,358)
Total non current	\$-	\$-
Total deferred income taxes	\$-	\$-

ASC 740 requires that a valuation allowance be established when it is more-likely-than-not that all or a portion of a deferred tax asset will not be realized. Changes in valuation allowances from period-to-period are included in the tax provision in the period of change. In determining whether a valuation allowance is required, we take into account all evidence with regard to the utilization of a deferred tax asset including past earnings history, expected future earnings, the character and jurisdiction of such earnings, unsettled circumstances that, if unfavorably resolved, would adversely affect utilization of a deferred tax asset, carryback and carryforward periods, and tax strategies that could potentially enhance the likelihood of realization of a deferred tax asset. Management has evaluated the available evidence about future taxable income and other possible sources of realization of deferred tax assets and has established a valuation allowance of approximately \$57 million at December 31, 2016 and \$57 million at December 31, 2015. The valuation allowance as of December 31, 2016 and 2015 includes approximately \$2.7 million for net operating loss carry forwards that relate to stock compensation expense for income tax reporting purposes that upon realization, would be recorded as additional paid-in capital. The valuation allowance reduces deferred tax assets to an amount that management believes will more likely than not be realized.

F-11

The components of the income tax provision (benefit) are as follows (in thousands):

	Years Ended	
	December 31,	
	2016	2015
Provision (benefit) for income taxes		
Current	\$(56)	\$(192)
Deferred		\$-
Income tax provision (benefit)	\$(56)	\$(192)

The 2016 and 2015 income tax benefits result from the Australian refundable research and development tax credit as explained in Note 7.

We have accumulated approximately \$148 million in federal and \$14 million in state net operating loss carryforwards (“NOLs”) and approximately \$6 million of research and development and alternative minimum tax credit carryforwards. The federal NOLs expire between 2024 and 2036. The Arizona state NOL’s expire between 2022 and 2036. The availability of these NOL’s to offset future taxable income could be limited in the event of a change in ownership, as defined in Section 382 of the Internal Revenue Code.

A reconciliation of the difference between the provision (benefit) for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows for the years ended December 31, 2016 and 2015:

	Years Ended	
	December 31,	
	2016	2015
Income tax provision (benefit) at statutory rate	\$(547)	\$(942)
State income taxes	\$(24 )	\$(94 )
Other	\$(139)	\$(205)
Change in valuation allowance	\$654	\$497
Net provision (benefit)	\$(56 )	\$(744)

## 5. STOCKHOLDERS’ EQUITY

In May 2006, our stockholders approved the 2005 Equity Incentive Plan (the “2005 Plan”) and reserved 2,000,000 shares of our common stock for issuance. Our stockholders approved the reservation of an additional 1,750,000 shares of common stock for issuance under the 2005 Plan, which increased the total shares available for grant under the 2005 Plan to 3,750,000 shares. The 2005 Plan expired in April 2015. In June 2015, our stockholders approved the 2015 Equity Incentive Plan (the “2015 Plan”) and reserved 1,000,000 shares of our common stock for issuance. At December



31, 2016, no shares remained available to grant under the 2015 Plan (the 2005 plan and the 2015 plan are collectively referred to as “The Plans”). Two types of options may be granted under the Plans: options intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code (the “Code”) and other options not specifically authorized or qualified for favorable income tax treatment by the Code. All eligible employees may receive more than one type of option. Any director or consultant who is not an employee of the Company shall be eligible to receive only nonqualified stock options under the Plans.

F-12

The Plans provide that in the event of a takeover or merger of the Company in which 100% of the equity of the Company is purchased or a sale of all or substantially all of the Company's assets, 75% of all unvested employee options will vest immediately and the remaining 25% will vest over the following twelve month period. If an employee or holder of stock options is terminated as a result of or subsequent to the acquisition, 100% of that individual's stock option will vest immediately upon employment termination.

We used the Black-Scholes model with the following assumptions to determine the total fair value of \$35,000 and \$174,000 for options to purchase 280,000 and 1,210,000 shares of our common stock issued during 2016 and 2015, respectively.

	2016		2015	
Risk free interest rate	1.5	%	1.6	%
Volatility	100	%	100	%
Expected term from vesting	4.5 Years		4.4 Years	
Dividend yield	0	%	0	%

### Summary

Non-cash stock compensation cost for the year ended December 31, 2016 and 2015 totaled \$35,000 and \$174,000, respectively, and was recorded as a general and administrative expense in the Statement of Operations.

No options were exercised in the years ended December 31, 2016 and 2015.

At December 31, 2016, there was no remaining unamortized non-cash stock compensation costs.

A summary of option activity under our stock option plans for the years ended December 31, 2016 and 2015 is as follows:

	2016		2015	
Number of Options	Number of Options	Weighted average exercise price	Number of Options	Weighted average exercise price
				Weighted average remaining contractual term

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

					(years)
Options outstanding at the beginning of the year:	4,162,706	\$ 0.81	3,022,706	\$ 1.06	
Granted	280,000	\$ 0.86	1,210,000	\$ 0.22	
Exercised	-		-		
Expired/Forfeited	(831,000 )	\$ 2.47	(70,000 )	\$ 1.31	
Outstanding at end of year	3,611,706	\$ 0.37	4,162,706	\$ 0.81	5.58
Options exercisable at year-end	3,611,706	\$ 0.37	4,031,039	\$ 0.83	5.58
Options vested and expected to vest at year end	3,611,706	\$ 0.37	4,075,808	\$ 0.82	5.52

F-13

The Company had no unvested common stock share awards as of December 31, 2016, or December 31, 2015, and no common stock awards were made in 2016 or 2015.

It is the Company's policy to issue options from stockholder approved incentive plans. However, if the options are issued as an inducement for an individual to join the Company, the Company may issue stock options outside of stockholder approved plans. The options granted to employees under stockholder approved incentive plans have a ten-year term and normally vest over a two to four-year period of service. All stock options are granted with an exercise price equal to the current market value on the date of grant and, accordingly, stock options have no intrinsic value on the date of grant. Based on the closing market price of the Company's common stock at December 31, 2016 of \$0.07, stock options exercisable or expected to vest at December 31, 2016, have an intrinsic value of \$2,000.

## **6.COMMITMENTS**

Rent expense for the years ended December 31, 2016 and 2015, was \$69,000 and \$70,000, respectively.

In 2007, the Company entered into a lease for 17,000 square feet of space in a Tempe, Arizona office and research facility. The term of this lease was sixty months from March 1, 2008. In January of 2013, this lease was amended to extend the lease to February 28, 2015, with the rentable square feet of space reduced to 2,845 square feet and monthly rental payments of approximately \$4,400 plus a proportionate share of building operating expenses and property taxes. This lease has been extended to May 31, 2017.

## **7.Australian Refundable Research & Development Credit**

In March 2014, LipimetiX Development LLC, (Now LipimetiX Development, Inc. - see Note 9 in the financial statements included in this Annual Report on Form 10-K) 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 either 43.5% or 45% (depending on the tax period) of qualified expenditures. Subsequent to the end of its Australian tax years, Lipimetix Australia Pty Ltd intends to submit claims for a refundable research and development tax credit. The transitional Australian tax periods/years granted for Lipimetix Australia Pty Ltd end on June 30, 2014, December 31, 2014 and thereafter December 31 of each succeeding year. For the tax year ended June 30, 2014, Lipimetix Australia Pty Ltd received a refundable research and development tax credit of AUD\$227,000. For the tax years ended December 31, 2014 and 2015 Lipimetix Australia Pty Ltd received a refundable research and development tax credit of AUD\$301,000 and AUD\$189,000, respectively, and at December 31, 2016 a AUD\$78,000 refundable research and development tax credit has been recorded by Lipimetix Australia Pty Ltd, as it is more likely than not that the recorded refundable research and development tax credit at December 31, 2016 will be approved and received.

## **8. AUTHORIZED PREFERRED STOCK**

We have 2,000,000 shares of authorized preferred stock, the terms of which may be fixed by our Board of Directors. We presently have no outstanding shares of preferred stock. Our Board of Directors has the authority, without stockholder approval, to create and issue one or more series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. If we raise additional funds to continue development of AEM-28 and its analogs, or operations, we may issue preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

F-14

## **9. 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 preferred stock), which have preferential distribution rights. On March 31, 2016, the Company converted 1,500,000 shares of its preferred stock into 120,000 shares of common stock, increasing its common stock ownership from 60% to 64%. As discussed below, the JV Series B-1 Preferred Stock issuance, because of the participating and conversion features of the preferred stock, effectively reduces the Company’s ownership in the JV to 59.3%.

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

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

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

LipimetiX, LLC was formed by the principals of Benu BioPharma, Inc. (“Benu”) and UABRF to commercialize UABRF’s intellectual property related to Apo E mimetic molecules, including AEM-28 and analogs. Benu is composed of Dennis I. Goldberg, Ph.D. 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.

F-15

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, two members appointed by the Company and one member appointed by the Series B-1 Preferred Stockholders. Non-development JV decisions, including the issuance of new equity, incurrence of debt, entry into strategic transactions, licenses or development agreements, sales of assets and liquidation, and approval of annual budgets, will be decided by a majority vote of the common and series B-1 Preferred Stock (voting on an “as converted” basis) stockholders.

The JV, on August 3, 2012, entered into a Management Agreement with Benu to manage JV development activities for a monthly fee of approximately \$63,000 during the twenty-seven month development period, and an Accounting Services Agreement with the Company to manage JV accounting and administrative functions. The services related to these agreements have been completed and new Management and Accounting Services Agreements were entered into effective June 1, 2016. The new monthly management fee is \$80,000 and the new monthly accounting services fee is \$10,000. However, no Management or Accounting Services fees are due or payable except to the extent funding is available, as unanimously approved by members of the JV Board of Directors and as reflected in the approved operating budget in effect at that time. In connection with the Series B-1 Preferred Stock issuance, Management Fees totaling \$300,000 and Accounting Fees totaling \$60,000 were paid in 2016.

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

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

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

The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. 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, 2016, losses incurred by the JV exceed the capital accounts of the JV. The Company has a revolving loan agreement with the joint venture to advance the joint



venture funds for operations in an amount not to exceed a net (net of expected tax credits or other funds obtained) of \$1,600,000, with the net amount due December 31, 2016. Losses incurred by the joint venture in excess of the capital accounts of the joint venture will be allocated to the Company to the extent of net outstanding advances. The additional JV capital from the Series B-1 Preferred Stock offering resulted in a decrease of \$946,000 in previously recognized losses of the JV by the Company, which had been recognized by the Company because of the existence of the outstanding revolving loan. At December 31, 2016, outstanding advances on the revolving loan agreement totaled \$1,594,000.

F-16

The joint venture incurred net operating expenses, prior to the elimination of intercompany transactions, of \$1,081,000 in 2016 and \$8,462,000 for the period from August 3, 2012 (inception) to December 31, 2016, of which \$137,000, after the previously described reduction in losses recognized of \$946,000, and \$6,850,000, 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 September 30, 2016, 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-28-14, 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 December 31, 2016 the Company would incur an additional loss of \$667,000 for the joint venture losses allocated to the common stock noncontrolling interests.

## **10. NOTE PAYABLE – FUNDRAISING ACTIVITIES**

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

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

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

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

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

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

#### **11. Contingency – Non-Compliance with Securities and Exchange Commission Reporting Requirements and OTCQB Market Requirements**

Our current level of funds available for operation has led to additional cost cutting, which included the decision to not engage an independent public accountant to audit and express an opinion on our December 31, 2016 and 2015 financial statements included in our Annual Report on Form 10-K filed with the SEC on March 15, 2017, or to review our Current Reports on Form 10-Q, as required by current SEC rules and regulations, and as required to be listed on the OTCQB Market. We cannot currently predict the response to these actions by the SEC or the OTCQB Market, nor the effects of their actions, including the possible effect on the trading of our common stock. The decision to not engage an independent public accountant to audit and express an opinion on our December 31, 2016 and 2015 financial statements or review our Current Reports on Form 10-Q could have a material adverse effect on the Company and its Stockholders.

F-18