

Capstone Therapeutics Corp.  
Form 10-K  
March 22, 2019

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

**FORM 10-K**

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

For the fiscal year ended December 31, 2018

**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

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*(Address of principal executive offices)*

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, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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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.

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

Large accelerated filer            Accelerated filer  
Non-accelerated filer            Smaller reporting company  
Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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, 2018 was approximately \$1,354,000. 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 15, 2019, was 54,385,411.



CAPSTONE THERAPEUTICS CORP.

FORM 10-K ANNUAL REPORT

YEAR ENDED DECEMBER 31, 2018

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## **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), other hyperlipidemic indications, and acute coronary syndrome/atherosclerosis regression. The initial AEM-28 development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting reduction of cholesterol and triglycerides.

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

Concurrent with the clinical development activities of AEM-28, the JV has performed pre-clinical studies that have identified analogs of AEM-28 and a new formulation, that have the potential of increased efficacy, higher human dose toleration and an extended composition of matter patent life (application filed with the U.S. Patent and Trademark Office in 2014). The JV’s current intent is to prioritize the development of an analog of AEM-28, specifically AEM-28-08.



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

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

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

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

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

Apolipoprotein E is a 299 amino acid protein that plays an important role in lipoprotein metabolism. Apolipoprotein E (Apo E) is in a class of protein that occurs throughout the body. Apo E is essential for the normal metabolism of cholesterol and triglycerides. After a meal, the postprandial (or post-meal) lipid load is packaged in lipoproteins and secreted into the blood stream. Apo E targets cholesterol and triglyceride rich lipoproteins to specific receptors in the liver, decreasing the levels in the blood. Elevated plasma cholesterol and triglycerides are independent risk factors for atherosclerosis, the buildup of cholesterol rich lesions and plaques in the arteries. AEM-28 is a 28 amino acid mimetic of Apo E and AEM-28 analogs are also 28 amino acid mimetics of Apo E (with an aminohexanoic acid group and a phospholipid), 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, as Apo E mimetics, have the potential to restore the ability of these atherogenic lipoproteins to be cleared from the plasma, completing the reverse cholesterol transport pathway, and thereby reducing cardiovascular risk. This is an important mechanism of action for AEM-28 and its analogs. Atherosclerosis is the major cause of cardiovascular disease, peripheral artery disease and cerebral artery disease, and can cause heart attack, loss of limbs and stroke. Defective lipid metabolism also plays an important role in the development of adult onset diabetes mellitus (Type 2 diabetes), and diabetics are particularly vulnerable to atherosclerosis, heart and peripheral artery diseases. Our joint venture has an Exclusive License Agreement with the University of Alabama at Birmingham Research Foundation for a broad domain of Apo E mimetic peptides, including AEM-28 and its analogs.

## **Company History**

Prior to November 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.)

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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 with LipimetiX Development, LLC, (now LipimetiX Development, Inc.) 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 or its analogs are 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, 2018, we utilize consultants to perform all 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 2018 and 2017 consisted primarily of work with or through our joint venture.

Through our joint venture, LipimetiX Development, Inc. (“JV”), we incurred expenses of \$1.4 million and \$1.2 million relating to AEM-28 or its analogs research efforts in 2018 and 2017, respectively. The JV has a development plan to pursue regulatory approval of AEM-28 or its analogs, as treatment for Homozygous Familial Hypercholesterolemia, other hyperlipidemic indications, and acute coronary syndrome/atherosclerosis regression. The initial AEM-28 development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting 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 analogs of AEM-28 and a new formulation, that have the potential of greater efficacy, higher human dose toleration and an extended composition of matter patent life (application filed in 2014).

## **Manufacturing**

Currently, third parties certified under Good Manufacturing Practices manufacture AEM-28 and its analogs 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 and its analogs 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, 2018, we utilized consultants to perform all 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. In prior years, none of our employees were represented by a union and we considered 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,” “continu



of these terms or other comparable terminology. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond our control and which could materially affect actual results, levels of activity, performance or achievements. Factors that may cause actual results to differ materially from current expectations, which we describe in more detail in this section titled "Risks," include, but are not limited to:

failure of the Company, or its joint venture, LipimetiX Development, Inc., to obtain additional funds to continue operations;

· the impact of the terms or conditions of agreements associated with funds obtained to fund operations;  
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 and its analogs;
- 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**

***Our Annual Reports for the years ending December 31, 2016 and 2015 on Form 10-K were originally 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 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 the Annual Report on Form 10-K filed with the SEC on March 15, 2017, as required by current SEC rules and regulations, and as required to be listed on the OTCQB Market. Although we filed an Amended Annual Report on Form 10-K/A with the SEC on October 30, 2017, which included the opinion of an independent registered public account on the December 31, 2016 and 2015 financial statements, 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.

In addition, we noted the previously issued June 30, 2017 and March 31, 2017 Form 10-Qs, which were not reviewed by an independent public accountant as of time of filing, included an error related to the classification of the convertible promissory notes payable of \$1,000,000 that were presented at March 31, 2017 as long-term when they were in fact current and at June 30, 2017 as current when in fact they were long-term. The Company does not intend to amend these previously issued Form 10-Qs for our June 30, 2017 and March 31, 2017 financial statements. At December 31, 2016 the convertible promissory notes payable were presented as long-term as they were in fact long-term at that date.

*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 a majority of the outstanding shares of our JV's common stock, on an as-converted basis, the noncontrolling stockholders of the JV have a majority of the JV's board of directors.***

Pursuant to a Stockholders Agreement, as amended, 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 three individuals designated by us. Consequently, our designees do not control 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 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 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 or its analogs. 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 and its analogs 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 and its analogs 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 abroad, and centers that conduct our clinical trials. We 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 \$0.02 during the period of January 1, 2004 through December 31, 2018) 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;
- 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 can vary 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, 2018, there were 54,385,411 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, 2018, we had options outstanding to purchase approximately 3,007,000 shares of our common stock, the exercise price of which ranges between \$0.05 per share to \$.82 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 or warrants are granted and exercised or additional stock is issued, the holders of our common stock

will experience further dilution. At December 31, 2018, no shares remain available to grant under the 2015 Equity Incentive Plan.

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2018, on January 30, 2018, the Company entered into the First Amendment to Securities Purchase, Loan and Security Agreement (the "Amendment") with BP Peptides, LLC ("Brookstone"). Brookstone currently owns approximately 34.1% of our outstanding common stock. Under the original Agreement (see Note 10 to the Financial Statements included in this Annual report on Form 10-K), interest on the Secured Debt was payable quarterly. The Amendment defers the payment of interest until the Secured Debt's maturity, October 15, 2020. In consideration for the deferral, the Company issued a Warrant to Brookstone to purchase up to 6,321,930 shares of the Company's Common Stock with an exercise price of \$.075 per share. The warrant expires October 15, 2025 and provides for quarterly vesting of shares in amounts approximately equal to the amount of quarterly interest payable that would have been payable under the Agreement, converted into shares at \$.075. At December 31, 2018 2,436,811 shares are fully vested and exercisable.

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.

In April 2017, our Board adopted a Tax Benefit Preservation Plan (“Benefit Plan”) with Computershare, pursuant to which each outstanding share of our common stock has attached one preferred stock purchase right. Each share of our common stock subsequently issued prior to the expiration of the Benefit Plan will likewise have attached one right. Under specified circumstances involving an “ownership change,” as defined in Section 382 of the Internal Revenue Code (the “Code”), the right under the Benefit Plan that attaches to each share of our common stock will entitle the holder thereof to purchase 1/100 of a share of our Series A preferred stock for a purchase price of \$5.00 (subject to adjustment), and to receive, upon exercise, shares of our common stock having a value equal to two times the exercise price of the right.

By adopting the Benefit Plan, our Board sought to protect our ability to use our net operating loss carryforwards and other tax attributes to reduce our future taxable income, if any (collectively, “Tax Benefits”). We view our Tax Benefits as highly valuable assets that are likely to inure to our benefit and the benefit of our stockholders if in the future we generate taxable income. However, if we experience an “ownership change,” our ability to use the Tax Benefits could be substantially limited, and the timing of the usage of the Tax Benefits could be substantially delayed, which could significantly impair the value of the Tax Benefits. The Benefit Plan is intended to act as a deterrent to persons acquiring our common stock in certain transactions that would constitute or contribute to such an “ownership change”

without the approval of our Board. The Benefit Plan expires December 31, 2020.

***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, 2018 we have loaned an additional \$1,720,000 (includes accrued interest of \$120,000) to the joint venture. In August 2017, the Company invested an additional \$1,000,000 through the purchase of 93,458 shares of series B-2 Preferred Stock of LipimetiX Development, Inc. Our cash investment in and loan 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 or loan.

***Our joint venture is unable to continue additional development of AEM or its analogs 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 February 28, 2020. Effective March 1, 2018, the square feet rented was reduced to 1,379 square feet. 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.

	2018		2017	
	High	Low	High	Low
1st Quarter	\$0.06	\$0.04	\$0.11	\$0.05
2nd Quarter	\$0.06	\$0.04	\$0.07	\$0.05
3rd Quarter	\$0.06	\$0.05	\$0.09	\$0.05
4th Quarter	\$0.06	\$0.02	\$0.07	\$0.04

As of February 15, 2019, 54,385,411 shares of our common stock were outstanding and held by approximately 347 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 a product 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 8 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, other hyperlipidemic indications, and acute coronary syndrome/atherosclerosis regression. The initial AEM-28 development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting reduction of cholesterol and triglycerides.

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

Concurrent with the clinical development activities of AEM-28, the JV has performed pre-clinical studies that have identified analogs of AEM-28, and a new formulation, that have the potential of increased efficacy, higher human dose toleration and an extended composition of matter patent life (application filed with the U.S. Patent and Trademark Office in 2014).

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

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

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



## Description of Current Peptide Drug Candidates.

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

Apolipoprotein E is a 299 amino acid protein that plays an important role in lipoprotein metabolism. Apolipoprotein E (Apo E) is in a class of protein that occurs throughout the body. Apo E is essential for the normal metabolism of cholesterol and triglycerides. After a meal, the postprandial (or post-meal) lipid load is packaged in lipoproteins and secreted into the blood stream. Apo E targets cholesterol and triglyceride rich lipoproteins to specific receptors in the liver, decreasing the levels in the blood. Elevated plasma cholesterol and triglycerides are independent risk factors for atherosclerosis, the buildup of cholesterol rich lesions and plaques in the arteries. AEM-28 is a 28 amino acid mimetic of Apo E and AEM-28 analogs are also 28 amino acid mimetics of Apo E (with an aminohexanoic acid group and a phospholipid), 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, as Apo E mimetics, have the potential to restore the ability of these atherogenic lipoproteins to be cleared from the plasma, completing the reverse cholesterol transport pathway, and thereby reducing cardiovascular risk. This is an important mechanism of action for AEM-28 and its analogs. Atherosclerosis is the major cause of cardiovascular disease, peripheral artery disease and cerebral artery disease, and can cause heart attack, loss of limbs and stroke. Defective lipid metabolism also plays an important role in the development of adult onset diabetes mellitus (Type 2 diabetes), and diabetics are particularly vulnerable to atherosclerosis, heart and peripheral artery diseases. Our joint venture has an Exclusive License Agreement with the University of Alabama at Birmingham Research Foundation for a broad domain of Apo E mimetic peptides, including AEM-28 and its analogs.

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## 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 \$38 million at December 31, 2018.

In March 2014, LipimetiX Development, LLC, now LipimetiX Development, Inc., (see Note 8 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, 2015, 2016 and 2017 refundable research and development tax credits of AUD\$301,000, AUD\$188,000, AUD\$84,000 and AUD\$42,000, respectively, were received by LipimetiX Australia Pty Ltd. At December 31, 2018, a refundable research and development tax credit of AUD\$4,000 has been accrued, as it is more likely than not, that the recorded refundable research and development tax credit at December 31, 2018 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, 2018, accumulated amortization totaled \$1,006,000. 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 and its analogs 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, 2018, 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 patent license rights. As discussed in Note 8 to the Financial Statements included in this Annual Report on Form 10-K, in August 2017, the Company purchased 93,458 shares of LipimetiX Development, Inc.'s Series B-2 Preferred Stock for \$1,000,000. Neither the Company nor the noncontrolling interests have an obligation to contribute additional funds to the joint venture or to assume any joint venture liabilities or to provide a guarantee of either joint venture performance or any joint venture liability. The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. Joint venture losses were recorded on the basis of common ownership equity interests until common ownership equity was reduced to \$0. Subsequent joint venture losses were allocated to the Series A 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, 2018, losses incurred by the JV exceeded the capital accounts of the JV. The Company has a revolving loan agreement with the joint venture and has advanced the joint venture funds for operations, with the net amount due December 31, 2016. As described in Note 8 to the Financial Statements included in this Annual Report on Form 10-K, the due date of the revolving loan has been extended to July 15, 2020, with early payment required upon certain additional funding of the joint venture by non-affiliated parties. Losses incurred by the joint venture in excess of the capital accounts of the joint venture will be allocated to the Company to the extent of net outstanding advances.

*Revenue Accounting:*

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASC 606") No. 2014-09 "Revenue from Contracts from Customers". The Company adopted ASC 606 effective January 1, 2018 and as no revenue had been recognized under the old standard, no transition was required. Pursuant to ASC 606, revenue is recognized by the Company when a customer obtains control of promised goods or services. The amount of revenue that is recorded reflects the consideration that the Company expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

*Upfront License Fees:* If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, upfront

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

## Recent Accounting Pronouncements

*Leases:* In February 2016 the FASB issued ASU 2016-02 *Leases (Topic 842)* and subsequently amended the guidance relating largely to transition considerations under the standard in January 2018 and July 2018. The objective of this update is to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those annual periods and is to be applied utilizing a modified retrospective approach. The Company believes the guidance will not have a material impact on its financial statements.

*Cooperation Agreement:* In May 2018 the Company's joint venture ("JV") entered into an agreement to cooperate with Anji Pharmaceuticals Inc. ("ANJI") (see Note 12 to the Financial Statements included in this Annual Report on Form 10-K) in the development of AEM-28 and its analogs. The JV entered into a License Agreement (the "Sub-License") with ANJI to sublicense, under its Exclusive License Agreement with the UAB Research Foundation, the use of the JV's AEM-28 and analogs intellectual property in the Territory of the People's Republic of China, Taiwan and Hong Kong (the "Territory"). As both parties intend to develop AEM-28 and its analogs, conducting independent development activities would result in both parties performing the same or similar pre-clinical work and clinical trial drug development. As such, the parties agreed to cooperate by the JV agreeing to perform certain preclinical work at its expense and for ANJI to cover the cost of clinical trial drug development. For efficiency and cost effectiveness the JV has agreed to manage the initial clinical trial drug development. Accordingly, the vendors performing the clinical trial drug development will bill the JV and ANJI will reimburse the JV. As provided for in ASC 606 and ASC 808 Collaborative Arrangements, the JV will net the reimbursements against the clinical trial drug development costs in Operating Expenses – Research & Development in the Consolidated Statements of Operations and the cash flow effect will be shown net in Operating Activities – Net Loss in the Consolidated Statements of Cash Flows in the Financial Statements included in this Annual Report on Form 10-K. Activity under the Cooperation Agreement as of December 31, 2018 totaled \$52,000 and were all costs of ANJI. For the year ended December 31, 2018, Cooperation Agreement costs and reimbursement activity of \$52,000 has been shown net and, accordingly, the Cooperation Agreement had no impact on the Consolidated Statements of Operations at December 31, 2018.

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

## Results of Operations Comparing Year Ended December 31, 2018 and 2017.

*Sublicense Revenue:* As described in Note 12 to the Financial Statements included in this Annual Report on Form 10-K, the JV entered into a License Agreement (the "Sub-License") with Anji Pharmaceuticals Inc. ("ANJI") to

sublicense, under its Exclusive License Agreement with the UAB Research Foundation, the use of the JV's AEM-28 and analogs intellectual property in the Territory of the People's Republic of China, Taiwan and Hong Kong (the "Territory"). The Sub-License calls for an initial payment of \$2,000,000, payment of a royalty on future Net Sales in the Territory and cash milestone payments based on future clinical/regulatory events. ANJI will perform all development activities allowed under the Sub-License in the Territory at its sole cost and expense. The JV recorded the receipt of the \$2,000,000 payment as revenue in the second quarter of 2018. Transaction costs related to the sublicense totaled \$254,000 and are separately stated on the Consolidated Statement of Operations included in the Financial Statements included in this annual Report on Form 10-K.

*General and Administrative ("G&A") Expenses:* G&A expenses related to our ongoing operations were \$554,000 in 2018 compared to \$641,000 in the 2017. G&A expenses decreased primarily due to higher accounting fees in 2017.

*Research and Development Expenses:* Research and development expenses were \$1,373,000 for 2018 compared to \$1,039,000 for 2017. Our research and development expenses increased in 2018 because of additional funds being available. Our research and development expenses continue to reflect reduced spending as our development activities of AEM-28 and its analogs were limited, as we attempt to obtain additional funding.

*Interest and other income (expense), net:* Interest and other income (expense), net was (\$251,000) for 2018 compared to (\$111,000) for 2017. The increase in expense in 2018 is interest recorded on the Secured Debt, as described in Note 10 included in the Financial Statements included in this Annual Report on Form 10-K, and on the issuance of Warrants, described in Note 11 included in the Financial Statements included in this Annual Report on Form 10-K.

*Income Tax Benefit:* Income tax benefit in 2018 and 2017 consisted of a refundable Australian research and development tax credit, as described in Notes 3 and 6 to the Financial Statements included in this Annual Report on Form 10-K, related to our joint ventures' Australian activities. Additionally, in 2018 the Company recorded a \$49,000 AMT refundable tax credit, as provided for in the Tax Cuts and Jobs Act.

*Net Loss attributable to Capstone Therapeutics stockholders:* We recorded a net loss for 2018 of \$.4 million compared to a net loss of \$1.8 million for 2017. The change is primarily due to the receipt of sublicense revenue partially offset by increased research and development spending in 2018 because of additional funds being available. Our operations and the development activities of AEM-28 and its analogs were limited, as we attempt to obtain additional funding.

#### **Results of Operations Comparing Year Ended December 31, 2017 and 2016.**

*General and Administrative (“G&A”) Expenses:* G&A expenses related to our ongoing operations were \$641,000 in 2017 compared to \$543,000 in 2016. Administration expenses increased primarily due to audit fees paid in 2017 to our independent registered public accountant for the audits of our 2016 and 2015 financial statements.

*Research and Development Expenses:* Research and development expenses were \$1,039,000 for 2017 compared to \$1,041,000 for 2016. Our research and development expenses in 2017 and 2016 included the operating expenses of LipimetiX Development, Inc., which totaled (net of intercompany transactions) \$1,039,000 for 2017, and \$1,021,000 for 2016. Our research and development expenses reflect spending of funds from the JV Series B-1 Preferred Stock and Warrant offering in August 2016 and the Company's purchase of JV Series B-2 Preferred Stock, as described in Notes 8 and 10 to the Financial Statements included in this Annual Report on Form 10-K. Our future development activities will be limited, as we attempt to obtain additional funding.

*Interest and Other Expenses (Income), Net:* Interest and Other Expenses (Income), Net, increased from \$81,000 net expense in 2016 to \$111,000 net expense in 2017 due to interest accrued on the Convertible Promissory Notes Payable and Secured Debt, as described in Notes 9 and 10 to the Financial Statements included in this Annual Report on Form 10-K.



*Income Tax Benefit:* Income tax benefit in 2017 and 2016 consisted of a refundable Australian research and development tax credit, as described in Notes 3 and 6 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 2017 of \$1.8 million, compared to a net loss of \$.7 million (net of \$.9 million allocated to the Series B-1 Preferred Stock ownership interest) in 2016. Net loss includes operations of LipimetiX Development, Inc. Our expenses reflect spending by the JV of funds from the JV Series B-1 Preferred Stock and Warrant offering in August 2016 and the Company's purchase of JV Series B-2 Preferred Stock, as described in Notes 8 and 10 to the Financial Statements included in this Annual Report on Form 10-K. Our future development activities of AEM-28 and its analogs, including AEM-28-08, will be limited as we attempt to obtain additional funding.

## Liquidity and Capital Resources

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

On August 3, 2012, we entered into a joint venture, to develop Apo E mimetic peptide AEM-28 and its analogs. We contributed \$6.0 million and through December 31, 2018 we have loaned an additional \$1,720,000 (including deferred interest of \$120,000) to the JV. The JV raised \$1,012,000 (\$946,000 net of issuance costs) in the JV's Series B-1 Preferred Stock and Warrant offering in August 2016. As described in Note 10 to the Financial Statements included in this Annual Report on Form 10-K, the Company on July 14, 2017, raised \$3,440,000, with net proceeds of approximately \$2,074,000, after paying off the Convertible Promissory Notes described in Note 9 to the Financial Statements included in this Annual Report on Form 10-K, and transaction costs of \$287,000. As disclosed in Note 12 to the Financial Statements included in this Annual Report on Form 10-K, on May 2, 2018, our JV entered into a License Agreement which resulted in the receipt of a \$2,000,000 nonrefundable payment (\$1,746,000 net of transaction costs). At December 31, 2018, we had cash and cash equivalents of \$1,341,000, of which \$1,093,000 is held by our JV.

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

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

Funding permitting, our planned operations in 2019 consist of continuing monitoring and participating in the management of the JV's development activities.

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

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

As discussed in Note 10 to the Financial Statements included in this Annual Report on Form 10-K, on July 14, 2017, the Company received a secured loan of \$2,427,500, due October 15, 2020, from BP Peptides, LLC, an entity that at December 31, 2018 owns approximately 34.1% of the Company's common stock. Interest on the secured loan, at a rate of 6% per annum, is payable on the maturity date of the secured loan. The 2nd Amendment provides for additional advances to the Company. The advances made and interest thereon, will be will increase the amount due on the maturity date of the secured loan.

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

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, 2018 and December 31, 2017 consolidated statements of operations, changes in equity and cash flows for each of the years in the two-year period ended December 31, 2018, 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, 2018.

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, 2018, 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**

As discussed in Note 10 to the Financial Statements included in this Annual Report on Form 10-K, on July 14, 2017, the Company received a secured loan of \$2,427,500, due October 15, 2020, from BP Peptides, LLC (“Brookstone”), an entity that, effective July 14, 2017, owned approximately 34.1% of the Company’s outstanding common stock. On July 14, 2017, the Company’s Board of Directors (“Board”) voted to expand the size of the Board from three to five members. On July 14, 2017, Mr. Matthew E. Lipman was appointed by the Board to fill the vacancy in Class II of the Board and Mr. Michael M. Toporek was appointed by the Board to fill the vacancy in Class III of the Board. The Board has determined that Mr. Matthew E. Lipman will serve on the Audit Committee of the Board and Mr. Michael M. Toporek will serve on the Compensation Committee of the Board. Mr. Matthew E. Lipman and Mr. Michael M. Toporek were introduced and recommended to the Board as nominees for director by Brookstone. A provision in the Agreement entered into with Brookstone requires the Company to nominate two candidates for a director position that have been recommended by Brookstone as long as Brookstone beneficially owns over 20% of the Company’s outstanding common stock and to nominate one candidate for a director position that has been recommended by Brookstone as long as Brookstone beneficially owns over 5% but less than 20% of the Company’s outstanding common stock.

John M. Holliman, III (3)

John M. Holliman III, 65, 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-five 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., 78, 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., 79, 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, and not-for-profits, Junior Achievement of Washington and the NOVIM Group. 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.

Michael M. Toporek (2)

Michael M. Toporek, 55, has served as a director since July 14, 2017. Mr. Toporek has served as a director of Mechanical Technology, Incorporated (MKTY) since October 21, 2016. Since 2003, Mr. Toporek has served as the Managing General Partner of Brookstone Partners, a lower middle market private equity firm based in New York and an affiliate of BV Peptides, LLC. Prior to founding Brookstone Partners in 2003, Mr. Toporek was both an active principal investor and an investment banker. Mr. Toporek began his career in Chemical Bank's Investment Banking Group, later joined Dillon, Read and Co., which became UBS Warburg Securities Ltd. during his tenure, and SG Cowen and Company. Mr. Toporek currently serves on the Board of Trustees of Harlem Academy. Mr. Toporek has a B.A. in Economics and an M.B.A from the University of Chicago. Mr. Toporek brings strategic and financial expertise to the Board as a result of his experience with Brookstone Partners, which the Board believes qualifies him to serve as a director.

Matthew E. Lipman (1)

Matthew E. Lipman, 40, has served as a director since July 14, 2017. Since 2004, Mr. Lipman has served as Managing Director of Brookstone Partners, a lower middle market private equity firm based in New York and an affiliate of BV Peptides, LLC. Mr. Lipman's responsibilities at Brookstone Partners include identifying and evaluating investment opportunities, performing transaction due diligence, managing the capital structure of portfolio companies and working with management teams to implement operational and growth strategies. In addition, Mr. Lipman is responsible for executing add-on acquisitions and other portfolio company-related strategic projects. From July 2001 through June 2004, Mr. Lipman was an analyst in the mergers and acquisitions group at UBS Financial Services Inc. responsible for formulating and executing on complex merger, acquisition and financing strategies for Fortune 500 companies in the industrial, consumer products and healthcare sectors. Mr. Lipman currently serves on the Board of Directors of Instone, LLC and Denison Pharmaceuticals, LLC. Mr. Lipman has a B.S. in Business Administration from Babson College. Mr. Lipman brings over 15 years of experience working with companies to establish growth strategies and execute acquisitions, is proficient in reading and understanding financial statements, generally accepted accounting principles and internal controls as a direct result of his investment experience evaluating companies for potential investments, the management of financial reporting and capital structure for three portfolio companies, as well as relevant experience in board service, which the Board believes qualifies him to serve as a director.

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(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 Dr. Feldman. On July 14, 2017 Mr. Lipman joined the Audit Committee.

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 and Dr. Feldman 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	65	Executive Chairman and Principal Executive Officer
Randolph C. Steer, MD, Ph.D.	69	Consultant
Les M. Taeger	68	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 Bio-Techne Corporation 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, 2018.

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.

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 M. 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	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Fredric J. Feldman, Ph.D.	10,000	-	-	-	-	10,000	20,000
Elwood D. Howse, Jr.	10,000	-	-	-	-	10,000	20,000

During the year ended December 31, 2018, the Company did not pay Directors' Board fees to Mr. Holliman, Mr. Toporek or Mr. Lipman. In 2018, Mr. Howse and Dr. Feldman were each paid Board Fees of \$10,000 in cash and each earned an additional Board Fee of \$10,000, payable July 15, 2020, or earlier if certain transactions occur. All directors are eligible for a grant of non-qualified stock options pursuant to the Company's 2015 Equity Incentive Plan. The Company did not grant any options to directors in 2018.



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

Name	Option Awards		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#) Exercisable	Options Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#) Unexercisable			
(a)	(b)	(c)	(d)	(e)	(f)
<b>John M. Holliman, III</b>	125,000			0.45	5/8/2019
	100,000			0.82	2/4/2020
	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	2/6/2024
	50,000			0.17	4/10/2025
	200,000			0.25	6/19/2025
	100,000			0.12	12/18/2025
<b>Various directors:</b>					
(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)(3)	35,000			0.17	5/18/2022
(1)(3)	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
(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, if any, 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. 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 continued as an employee, but his base compensation was reduced from \$242,000 per year to \$120,000. His salary was \$100,000 per year effective 3/1/2017 (Commencing March 1, 2018, \$60,000 per year will be paid and \$40,000 will be deferred until July 15, 2020 or until certain transactions occur.). Effective January 1, 2018, Mr. Taeger ceased being an employee and has continued his services as a consultant. 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 2018 Dr. Steer received no consulting compensation. In 2018, consulting compensation for Mr. Holliman was \$129,000, from the Company \$100,000 (\$21,000 paid and \$79,000 deferred until July 15, 2020 or until certain transactions occur) and \$29,000 from our joint venture. Dr. Steer's compensation will continue to be minimal, until additional funding is received by the Company. Additionally, all other employees and consultants cash compensation has been reduced 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 will be determined based on the position and competitive factors, as well as substantial compensation reductions effective October 31, 2011.

### **Stock Option Grants**

In 2018, the Company granted no options to employees and there are currently no options available to grant in the 2015 Equity Incentive Plan.

### **Common Stock Awards**

The Company did not grant any common stock awards in 2018.

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

In 2018, we had no group health, dental, life, and disability programs. 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 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; however, no amounts have been earned as of December 31, 2018.

### **Holliman Option**

On October 27, 2017 the Board granted Mr. Holliman an option to purchase 14,126 shares of the LipimetiX Development, Inc. (“JV”) Series B-2 Preferred Stock it currently owns, at an exercise price of \$10.70 per share, subject to adjustment and other terms consistent with the Series B-2 Preferred Stock, as described in Note 8 to the Financial Statements included in the Annual Report on Form 10-K. The option is exercisable for a five-year period from the date of grant.

**Summary Compensation Table**

The following table sets forth, with respect to the years ended December 31, 2018, 2017 and 2016, 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	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
(a)	(b)	(\$) (c)	(\$) (d)	(\$) (e)	(\$) (f)	(\$) (g)	(\$) (h)	(\$) (i)(2)	(\$) (j)
John M. Holliman, III Executive Chairman (Principal Executive Officer)	2018	\$50,000	-	-	-	-	-	79,000	\$129,000
	2017	\$106,000	-	-	-	-	-	-	\$106,000
	2016	\$47,000	-	-	\$4,000	-	-	4,000 (1)	\$55,000
Randolph C. Steer, MD, Ph.D., Consultant (former President)	2018	-	-	-	-	-	-	-	-
	2017	\$56,000	-	-	-	-	-	-	\$56,000
	2016	\$4,000	-	-	-	-	-	-	\$4,000
Les M. Taeger Chief Financial Officer (Principal Financial Officer)	2018	\$50,000	-	-	\$-	-	-	33,000	\$83,000
	2017	\$111,000	-	-	-	-	-	-	\$111,000
	2016	\$79,000	-	-	-	-	-	-	\$79,000

Mr. Holliman is a member of the Board of Directors and as a director, received compensation of \$0, \$0 and \$4,000, in cash, in 2018, 2017 and 2016, respectively. Mr. Holliman received total director's compensation (Board fees and option grants) of \$0, \$0 and \$8,000 in 2018, 2017 and 2016, respectively, as more fully described in the

1. Compensation of Directors section of this Annual Report on Form 10-K. 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 the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on October 30, 2017.

2.

In 2018 Mr. Holliman earned \$79,000 and Mr. Taeger earned \$33,000 in compensation, payment of which is deferred until July 15, 2020 or upon the occurrence of certain transactions.

**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 of Shares of Stock or Units #	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)
	-	-	-	\$ -	-

No options or stock awards were granted in 2018 and at December 31, 2018 no shares remained available to grant or award in the 2015 Equity Incentive Plan.



**Outstanding Equity Awards at Fiscal Year END**

Name	Option Awards		Option Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		
(a)	(b)	(c)	(e)	(f)
John M. Holliman	10000	-	0.42	1/1/2019
	125000	-	0.45	5/8/2019
	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.	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	50000	-	0.45	2/3/2019
	35000	-	0.82	2/4/2020
	25000	-	0.67	1/17/2021
	45000	-	0.17	5/18/2022



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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. While an employee, Mr. Taeger received medical, dental and other fringe benefits generally granted to the Company's senior management. Effective January 1, 2018 Mr. Taeger ceased being an employee and continued his services as a consultant, without fringe benefits.

Effective October 31, 2011, Mr. Taeger's annual base salary was reduced to from \$242,000 to \$120,000. Mr. Taeger's salary effective March 1, 2017 is \$100,000 per year, but commencing March 1, 2018, \$60,000 per year will be paid and \$40,000 will be deferred until July 15, 2020 or until certain transactions occur.

Mr. Holliman compensation is \$100,000 per year, with \$50,000 per year to be paid and \$50,000 to be deferred until July 15, 2020 or until certain transactions occur. Mr. Holliman received consulting cash compensation of \$29,000, of his \$50,000 cash compensation, in 2018, from our joint venture.

Dr. Steer received no consulting compensation in 2018. In 2019, consulting compensation for 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, 2018, all options held by named executive officers were vested and had no intrinsic value and accelerated vesting clauses, if triggered at December 31, 2018, 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 15, 2019 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 15, 2019, there were 54,385,411 shares of the Company's Common Stock outstanding.

Beneficial Owner	Beneficially Owned (1)	
	Number	Percent of Class
Fredric J. Feldman (2)	592,064	1.1
John M. Holliman, III (3)	1,365,170	2.5
Elwood D. Howse, Jr. (4)	589,203	1.1
Michael M. Toporek (7)	21,946,348	38.0
Matthew E. Lipman (7)	21,946,348	38.0
Randolph C. Steer (5)	548,298	1
Les M. Taeger (6)	488,574	0.9
BP Peptides, LLC (7)	21,946,348	38.0
Lloyd Miller, III (now Neil S. Subin)(8)	7,554,422	13.9
All directors and executive officers as a group (9)	25,529,657	42.4

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 366,500 shares Dr. Feldman has a right to acquire upon exercise of stock options. Voting and investment power shared with spouse.

(3) Includes 853,000 shares Mr. Holliman has a right to acquire upon exercise of stock options.

(4) Includes 366,500 shares Mr. Howse has a right to acquire upon exercise of stock options.

(5) Includes 503,000 shares Dr. Steer has a right to acquire upon exercise of stock options.

(6) Includes 394,000 shares Mr. Taeger has a right to acquire upon exercise of stock options.

The address of the principal office of BP Peptides, LLC, the Reporting Person, is 122 East 42<sup>nd</sup> Street, Suite 4305, New York, New York 10168. As discussed in Note 11 to the Financial Statements included in this Annual Report on Form 10-K, on July 14, 2017, the Company received a secured loan of \$2,427,500, due October 15, 2020, from BP Peptides, LLC (“Brookstone”), an entity that effective July 14, 2017 owns 18,541,197 shares of the Company’s common stock. On July 14, 2017, the Company’s Board of Directors (“Board”) voted to expand the size of the Board from three to five members. On July 14, 2017, Mr. Matthew E. Lipman was appointed by the Board to fill the vacancy in Class II of the Board and Mr. Michael M. Toporek was appointed by the Board to fill the vacancy in Class III of the Board. Mr. Matthew E. Lipman and Mr. Michael M. Toporek are affiliated with Brookstone and were introduced and recommended to the Board as nominees for director by Brookstone. A provision in the Securities Purchase, Loan and Security Agreement entered into with Brookstone, requires the Company to nominate two candidates for a director position that have been recommended by Brookstone as long as Brookstone beneficially owns over 20% of the Company’s outstanding common stock and to nominate one candidate for a director position that has been recommended by Brookstone as long as Brookstone beneficially owns over 5% but less than 20% of the Company’s outstanding common stock. The shares shown as beneficially owned by Michael M. Toporek and Mathew E. Lipman include 21,946,348 shares beneficially owned by BP Peptides, LLP.

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2018, on January 30, 2018, the Company entered into the First Amendment to Securities Purchase, Loan and Security Agreement (the “Amendment”) with BP Peptides, LLC (“Brookstone”). Under the original Agreement (see Note 10 in the Financial Statements included in this Annual Report on Form 10-K), interest on the Secured Debt was payable quarterly. The Amendment defers the payment of interest until the Secured Debt’s maturity, October 15, 2020. In consideration for the deferral, the Company issued a Warrant to Brookstone to purchase up to 6,321,930 shares of the Company’s Common Stock with an exercise price of \$.075 per share. The warrant expires October 15, 2025 and provides for quarterly vesting of shares in amounts approximately equal to the amount of quarterly interest payable that would have been payable under the Agreement, converted into shares at \$. 075. On February 15, 2019 Brookstone beneficially owns 3,405,151 of these Warrant shares.

(8) Lloyd Miller, III, is not a related party or otherwise affiliated with the Company, its directors or officers. The 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. Effective January 12, 2018 Mr. Neil S. Subin replaced the deceased Mr. Miller as president and manager of the Miller entities.

(9) Includes 5,888,151 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, 2018, aggregated into two categories - plans that have been approved by stockholders and plans that have not. See Note 6 to the Financial Statements included in this Annual Report on Form 10-K for additional information on our equity compensation plans.

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
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Plan Category	(a)	(b)	(c) (excluding securities reflected in column (a))
Equity Compensation Plans approved by Security Holders	3,007,000	\$ 0.29	0
Equity Compensation Plans not approved by Security Holders	N/A	N/A	N/A
Total	3,007,000	\$ 0.29	0

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2018, on January 30, 2018, the Company entered into the First Amendment to Securities Purchase, Loan and Security Agreement (the “Amendment”) with BP Peptides, LLC (“Brookstone”). Brookstone currently owns approximately 34.1% of our outstanding common stock. Under the original Agreement (see Note 10 to the Financial Statements included in this Annual report on Form 10-K), interest on the Secured Debt was payable quarterly. The Amendment defers the payment of interest until the Secured Debt’s maturity, October 15, 2020. In consideration for the deferral, the Company issued a Warrant to Brookstone to purchase up to 6,321,930 shares of the Company’s Common Stock with an exercise price of \$.075 per share. The warrant expires October 15, 2025 and provides for quarterly vesting of shares in amounts approximately equal to the amount of quarterly interest payable that would have been payable under the Agreement, converted into shares at \$.075. At December 31, 2018 2,436,811 shares are fully vested and exercisable.

### 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 three directors who are not independent directors 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 2018 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, except as disclosed below.

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2018, on January 30, 2018, the Company entered into the First Amendment to Securities Purchase, Loan and Security Agreement (the "Amendment") with BP Peptides, LLC ("Brookstone"). Brookstone currently owns approximately 34.1% of our outstanding common stock. Under the original Agreement (see Note 10 to the Financial Statements included in this Annual Report on Form 10-K), interest on the Secured Debt was payable quarterly. The Amendment defers the payment of interest until the Secured Debt's maturity, October 15, 2020. In consideration for the deferral, the Company issued a Warrant to Brookstone to purchase up to 6,321,930 shares of the Company's Common Stock with an exercise price of \$.075 per share. The warrant expires October 15, 2025 and provides for quarterly vesting of shares in amounts approximately equal to the amount of quarterly interest payable that would have been payable under the Agreement, converted into shares at \$.075. At December 31, 2018 2,436,811 shares are fully vested and exercisable.

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 did not engage an independent public accountant to audit our fiscal years ended December 31, 2016 or 2015 financial statements until July 14, 2017.

Type of Fee	Amount	
	2018	2017
Audit Fee (1)	\$64,000	\$128,000
Audit-Related Fees (2)	-	0
Total Audit and Audit-Related Fees	\$64,000	\$128,000
Tax Fees (3)	-	-
All Other Fees (4)	-	-
Total Fees	\$64,000	\$128,000



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- 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, 2018 and 2017 that are appropriately classified as "All Other Fees."

The Audit Committee has concluded that the services provided by the principal accounting firm 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 2018.

## 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. and Report of our Independent Registered Public Accounting Firm are presented in the “F” pages of this report:

Report of Independent Registered Public Accounting Firm.

Consolidated Balance Sheets - December 31, 2018 and 2017.

Consolidated Statements of Operations - Each of the years in the two-year period ended December 31, 2018.

Consolidated Statements of Changes in Equity - Each of the years in the two-year period ended December 31, 2018.

Consolidated Statements of Cash Flows - Each of the years in the two-year period ended December 31, 2018.

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 22, 2019 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 22, 2019
<u>/s/ Elwood D. Howse, Jr.</u> Elwood D. Howse, Jr.	Director	March 22, 2019
<u>/s/ Fredric J. Feldman</u> Fredric J. Feldman, Ph.D.	Director	March 22, 2019
<u>/s/ Michael M. Toporek</u> Michael M. Toporek	Director	March 22, 2019
<u>/s/ Matthew E. Lipman</u> Matthew E. Lipman	Director	March 22, 2019

/s/ Les M. Taeger

Les M. Taeger

Senior Vice President and Chief

March 22, 2019

Financial Officer (Principal Financial  
and Accounting Officer)

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**Capstone Therapeutics Corp. (“the Company”)**

**Exhibit Index to Annual Report on Form 10-K**

**For the Year Ended December 31, 2018**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>	<b><u>Incorporated by Reference To:</u></b>	<b>Filed or Furnished Herewith</b>
<u>3.1</u>	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 P	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”)	
<u>3.3</u>	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	
<u>3.4</u>	Second Amended and Restated Certificate of Incorporation as amended through June 22, 2015, 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	
<u>3.5</u>	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 P	Form of Indemnification Agreement (*)	Exhibit 10.16 to the Company’s January 1993 S-1	
<u>10.2</u>	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	
<u>10.3</u>	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	

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11, 2006 (the “January 11<sup>th</sup> 8-K”)

- |             |  |   |
|-------------|--|---|
| <u>10.4</u> | 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  |
| <u>10.5</u> | 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  |
| <u>10.6</u> | 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 |

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<u>10.7</u>	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
<u>10.8</u>	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
<u>10.9</u>	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
<u>10.10</u>	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
<u>10.11</u>	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
<u>10.12</u>	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
<u>10.13</u>	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
<u>10.14</u>	Capstone Therapeutics Corp. Joint Venture Bonus Plan (1)	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
<u>10.15</u>	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
<u>10.16</u>	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
<u>10.17</u>	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
<u>10.18</u>	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

Appendix A to the Company's Definitive  
Proxy Statement filed on Schedule 14A  
with the SEC on May 8, 2015

10.19 2015 Equity Incentive Plan

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<u>10.20</u>	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
<u>10.21</u>	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
<u>10.22</u>	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 June 26, 2015
<u>10.23</u>	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
<u>10.24</u>	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
<u>10.25</u>	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
<u>10.26</u>	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
<u>10.27</u>	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
<u>10.28</u>	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
<u>10.29</u>	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
<u>10.30</u>	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
<u>10.31</u>	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
<u>10.32</u>	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
<u>10.33</u>	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	Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the SEC on August 26, 2016

Herein

10.34 Securities Purchase, Loan and Security Agreement dated July 14, 2017, by and between Capstone Therapeutics Corp. and BP Peptides, LLC Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 17, 2017

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<u>10.35</u>	Promisary Note dated July 14, 2017, payable to BP Peptide, LLC	Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on July 17, 2017	
<u>10.36</u>	Registration Rights Agreement dated July 14, 2017, by and between Capstone Therapeutics Corp. and BP Peptides, LLC	Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on July 17, 2017	
<u>10.37</u>	Series B-2 Preferred Stock Purchase Agreement, dated August 11, 2017, by and between Capstone Therapeutics Corp. and LipimetiX Development, Inc.	Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2017	
<u>10.38</u>	First Amendment to the Amended and Restated Stockholders Agreement of LipimetiX Development, Inc., dated August 11, 2017	Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2017	
<u>10.39</u>	Joinder of August 25, 2016 Registration Rights Agreement of LipimetiX Development, Inc., dated August 11, 2017	Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2017	
<u>10.40</u>	Certificate of Amendment of Amended and Restated Certificate of Incorporation of LipimetiX Development, Inc.	Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2017	
<u>10.41</u>	First Amendment to Bylaws of LipimetiX Development, Inc., dated August 11, 2017	Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2017	
<u>10.42</u>	First Amendment to Securities Purchase Loan and Security Agreement dated January 30, 2018, by and between Capstone Therapeutics, Corp. and BP Peptides, LLC	Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 1, 2018	
<u>10.43</u>	Warrant to Purchase Common Stock dated January 30, 2018	Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on February 1, 2018	
<u>10.44</u>	License Agreement dated May 2, 2018 by and between LipimetiX Development, Inc. and Anji Pharmaceuticals Inc.	Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on May 7, 2018	
<u>31.1</u>	Certification of Principal Executive Officer Pursuant to Rule 13a -14(a) of the Securities Exchange Act of 1934, as amended		X
<u>31.2</u>	Certification of Principal Financial and Accounting Officer Pursuant to Rule 13a - 14(a) of the Securities Exchange Act of 1934, as amended		X
<u>32.1</u>	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350***		X

The following financial information from our Annual Report on Form 10-K for the fiscal year 2018, filed with the SEC on March 22, 2019 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as December 31, 2018 and 2017, (ii) the Consolidated Statements of Operations for the two years ended 2018 and 2017 (iii) the Consolidated Statements of Cash Flows for the two years ended December 31, 2018 and 2017 and (iv) Notes to Consolidated Financial Statements. \*\*\*

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(1) Management contract or compensatory plan or arrangement.

\* 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.

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## **FINANCIAL STATEMENTS**

### **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders  
Capstone Therapeutics Corp.

Tempe, Arizona

#### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Capstone Therapeutics Corp. (Company) as of December 31, 2018 and 2017, and the related statements of operations, stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of Capstone Therapeutics Corp. as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

#### **Basis for Opinion**

These financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risk of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also

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included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Eide Bailly LLP

We have served as Capstone Therapeutics Corp. auditor since 2017.

Denver, Colorado

March 22, 2019

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

	December 31, 2018	December 31, 2017
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$1,341	\$1,275
Other current assets	97	98
Total current assets	1,438	1,373
Patent license rights, net	39	196
Furniture and equipment, net	-	-
Total assets	\$1,477	\$1,569
<b>LIABILITIES AND EQUITY</b>		
Current liabilities		
Accounts payable	\$245	\$197
Other accrued liabilities	1	2
Total current liabilities	246	199
Long-term debt		
Secured Debt and accrued interest, net of unamortized issuance costs	2,475	2,249
Total long-term debt	2,475	2,249
Equity		
Capstone Therapeutics Corp. Stockholders' Equity		
Common Stock\$.0005 par value; 150,000,000 shares authorized; 54,385,411 shares outstanding December 31, 2018 and 2017	27	27
Additional paid-in capital	190,483	190,468
Accumulated deficit	(191,754)	(191,374)
Total Capstone Therapeutics Corp. stockholders' equity (deficit)	(1,244 )	(879 )
Noncontrolling interest		
Total equity	(1,244 )	(879 )
Total liabilities and equity	\$1,477	\$1,569

See notes to consolidated financial statements

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

	December 31,	
	2018	2017
SUBLICENSE REVENUE	\$2,000	\$—
OPERATING EXPENSES:		
Sublicense transaction costs	254	—
General and administrative	554	641
Research and development	1,373	1,039
Total operating expenses	2,181	1,680
Income (loss) after operating expenses	(181 )	(1,680 )
Interest and other income (expense), net	(251 )	(111 )
Income(loss) from operations before taxes	(432 )	(1,791 )
Income tax benefit	52	36
NET INCOME (LOSS)	(380 )	(1,755 )
Less: Net Income (Loss) attributable to the noncontrolling interest	—	—
Net Income (Loss) attributable to Capstone Therapeutics Corp. stockholders	\$(380 )	\$(1,755 )
Per Share Information:		
Net Income (Loss), basic and diluted, attributable to Capstone Therapeutic Corp. stockholders	\$(0.01 )	\$(0.04 )
Basic and diluted shares outstanding	54,385	47,173

*See notes to consolidated financial statements*

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

	Capstone Therapeutics Corp. Stockholders' Equity					
	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Non controlling Interest	Total
Balance December 31, 2016	40,885	\$ 20	\$ 189,477	\$ (189,619 )	\$ —	\$(122 )
Sale of Common Stock	13,500	7	1,006	—	—	1,013
Series B-2 Preferred Stock	—	—	(15 )	—	—	(15 )
Net loss	—	—	—	(1,755 )	—	(1,755)
Balance December 31, 2017	54,385	27	190,468	(191,374 )	—	(879 )
Stock-based compensation cost	—	—	15	—	—	15
Net loss	—	—	—	(380 )	—	(380 )
Balance December 31, 2018	54,385	\$ 27	\$ 190,483	\$ (191,754 )	\$ —	\$(1,244)

*See notes to consolidated financial statements*

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

	December 31,	
	2018	2017
<b>OPERATING ACTIVITIES</b>		
Net loss	\$(380 )	\$(1,755)
Non cash items:		
Amortization	157	205
Non-cash interest expense	238	68
Non-cash stock-based interest expense	15	—
Change in other operating items:		
Other current assets	1	26
Accounts payable	48	(52 )
Other accrued liabilities	(13 )	(53 )
Cash flows provided by (used in) operating activities	66	(1,561)
<b>INVESTING ACTIVITIES</b>		
Cash flows provided by investing activities	—	—
<b>FINANCING ACTIVITIES</b>		
Sale of Common Stock	—	1,013
LipimetiX Development, Inc. Series B-2 Preferred Stock transaction costs	—	(15 )
Pay-off of Convertible Promissory Notes	—	(1,000)
Issuance of Secured Debt, net of issuance costs of \$287	—	2,140
Cash flows provided by financing activities	—	2,138
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>66</b>	<b>577</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>1,275</b>	<b>698</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$1,341</b>	<b>\$1,275</b>

*See notes to 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), other hyperlipidemic indications, and acute coronary syndrome/atherosclerosis regression. The initial AEM-28 development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting reduction of cholesterol and triglycerides.

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.

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Concurrent with the clinical development activities of AEM-28, the JV has performed pre-clinical studies that have identified analogs of AEM-28, and a new formulation, that have the potential of increased efficacy, higher human dose toleration and an extended composition of matter patent life (application filed with the U.S. Patent and Trademark Office in 2014).

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

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

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

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

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

Apolipoprotein E is a 299 amino acid protein that plays an important role in lipoprotein metabolism. Apolipoprotein E (Apo E) is in a class of protein that occurs throughout the body. Apo E is essential for the normal metabolism of cholesterol and triglycerides. After a meal, the postprandial (or post-meal) lipid load is packaged in lipoproteins and secreted into the blood stream. Apo E targets cholesterol and triglyceride rich lipoproteins to specific receptors in the liver, decreasing the levels in the blood. Elevated plasma cholesterol and triglycerides are independent risk factors for atherosclerosis, the buildup of cholesterol rich lesions and plaques in the arteries. AEM-28 is a 28 amino acid mimetic of Apo E and AEM-28 analogs, are also 28 amino acid mimetics of Apo E (with an aminohexanoic acid group and a phospholipid), 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, as Apo E mimetics, have the potential to restore the ability of these atherogenic lipoproteins to be cleared from the plasma, completing the reverse cholesterol transport pathway, and thereby reducing cardiovascular risk. This is an important mechanism of action for AEM-28 and its analogs. Atherosclerosis is the major cause of cardiovascular disease, peripheral artery disease and cerebral artery disease, and can cause heart attack, loss of limbs and stroke. Defective lipid metabolism also plays an important role in the development of adult onset diabetes mellitus (Type 2 diabetes), and diabetics are particularly vulnerable to atherosclerosis, heart and peripheral artery diseases. Our joint venture has an Exclusive License Agreement with the University of Alabama at Birmingham Research Foundation for a broad domain of Apo E mimetic peptides, including AEM-28 and its analogs.

## **Company History**

Prior to November 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.

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On August 3, 2012, we entered into a joint venture with LipimetiX Development, LLC, (now LipimetiX Development, Inc.) (see Note 8 below) to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

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

OrthoLogic Corp. commenced doing business under the trade name of Capstone Therapeutics on October 1, 2008, and we formally changed our name from OrthoLogic Corp. to Capstone Therapeutics Corp. on May 21, 2010.

In these notes, references to “we”, “our”, “us”, the “Company”, “Capstone Therapeutics”, “Capstone”, and “OrthoLogic” refer to Capstone Therapeutics Corp. References to our joint venture or “JV”, refer to LipimetiX Development, Inc. (formerly LipimetiX Development, LLC).

**Basis of presentation, Going Concern, and Management’s Plans.** The accompanying 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 and its analogs or to continue operations. Accordingly, the Company has significantly reduced its development activities. The Company’s corporate strategy is to raise funds by possibly engaging in a strategic/merger transaction or conducting a private or public offering of debt or equity securities for capital. As described in Note 10 to the Financial Statements included in this Annual Report on Form 10-K, the Company, on July 14, 2017, raised \$3,440,000, with net proceeds of approximately \$2,074,000, after paying off the Convertible Promissory Notes described in Note 9 to the Financial Statements included in this Annual Report on Form 10-K, and transaction costs of \$287,000. (As discussed in Note 8 to the Financial Statements included in this Annual Report on Form 10-K, in August 2017, the Company used \$1,000,000 of the net proceeds to purchase 93,458 shares of LipimetiX Development, Inc.’s Series B-2 Preferred Stock.) The additional funds, as well as a commitment of additional funding from the same investor on an as needed basis of up to \$500,000 through an increase in its outstanding long-term debt, alleviated the substantial doubt about the entity’s ability to continue as a going concern; however, additional funds will be required for the joint venture to reach its development goals and for the Company to continue its planned operations

**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 valuation of our joint venture patent rights and accounting for stock-based compensation.

**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.

**Cash and cash equivalents.** Cash and cash equivalents consist of highly liquid investments with an original maturity of three months or less.

**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.

**Accounts Payable.** Accounts payable includes officer compensation of \$135,000 and \$23,000 at December 31, 2018 and 2017, respectively, that is payable the earlier of July 15, 2020, occurrence of certain transaction or approval by the Company's Board of Directors.

**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.

**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.

The Company recorded stock-based compensation of \$0 in 2018 and 2017. Accordingly, loss per weighted average basic and diluted shares outstanding were not affected by 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, 2018, no shares were determined to be outstanding and excluded from the calculation of loss per share because they were anti-dilutive. At December 31, 2018, options and warrants to purchase 3,007,000 and 6,321,930 shares, respectively, of our common stock, at exercise prices ranging from \$0.05 to \$.82 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, 2018 and 2017 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, 2018, tax years 2014 through 2018 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, 2018 and 2017, 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, 2018, accumulated amortization totaled \$1,006,000. 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. As discussed in Note 8 to the Financial Statements included in this Annual Report on Form 10-K, in August 2017, the Company purchased 93,458 shares of LipimetiX Development, Inc.’s Series B-2 Preferred Stock for \$1,000,000. Neither the Company nor the noncontrolling interests have an obligation to contribute additional funds to the joint venture or to assume any joint venture liabilities or to provide a guarantee of either joint venture performance or any joint venture liability. The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. Joint venture losses were recorded on the basis of common ownership equity interests until common ownership equity was reduced

to \$0. Subsequent joint venture losses were allocated to the Series A 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, 2018, losses incurred by the JV exceeded the capital accounts of the JV. The Company has a revolving loan agreement with the joint venture and advanced the joint venture funds for operations, with the net amount due December 31, 2016. As described in Note 8 to the Financial Statements included in this Annual Report on Form 10-K, the due date of the revolving loan has been extended to July 15, 2020, with early payment required upon certain additional funding of the joint venture by non-affiliated parties. Losses incurred by the joint venture in excess of the capital accounts of the joint venture will be allocated to the Company to the extent of net outstanding advances.

## Legal and Other Contingencies

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

Legal costs related to contingencies are expensed as incurred and were not material in either 2018 or 2017.

## Revenue Accounting

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASC 606”) No. 2014-09 “Revenue from Contracts from Customers”. The Company adopted ASC 606 effective January 1, 2018 and as no revenue was recognized under the old standard, no transition was required. Pursuant to ASC 606, revenue is recognized by the Company when a customer obtains control of promised goods or services. The amount of revenue that is recorded reflects the consideration that the Company expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

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

## Recent Accounting Pronouncements

Leases. In February 2016 the FASB issued ASU 2016-02 *Leases (Topic 842)* and subsequently amended the guidance relating largely to transition considerations under the standard in January 2018 and July 2018. The objective of this update is to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those annual periods and is to be applied utilizing a modified retrospective approach. The Company believes the guidance will not have a material impact on its financial statements.

*Cooperation Agreement.* In May 2018 the Company's joint venture ("JV") entered into an agreement to cooperate with Anji Pharmaceuticals Inc. ("ANJI") (see Note 12 to the Financial Statements included in this Annual Report on Form 10-K) in the development of AEM-28 and its analogs. The JV entered into a License Agreement (the "Sub-License") with ANJI to sublicense, under its Exclusive License Agreement with the UAB Research Foundation, the use of the JV's AEM-28 and analogs intellectual property in the Territory of the People's Republic of China, Taiwan and Hong Kong (the "Territory"). As both parties intend to develop AEM-28 and its analogs, conducting independent development activities would result in both parties performing the same or similar pre-clinical work and clinical trial drug development. As such, the parties agreed to cooperate by the JV agreeing to perform certain preclinical work at its expense and for ANJI to cover the cost of clinical trial drug development. For efficiency and cost effectiveness the JV has agreed to manage the initial clinical trial drug development. Accordingly, the vendors performing the clinical trial drug development will bill the JV and ANJI will reimburse the JV. As provided for in ASC 606 and ASC 808 Cooperation Arrangements, the JV will net the reimbursements against the clinical trial drug development costs in Operating Expenses – Research & Development in the Consolidated Statements of Operations and the cash flow effect will be shown net in Operating Activities – Net Loss in the Consolidated Statements of Cash Flows in the Financial Statements included in this Annual Report on Form 10-K. Activity under the Cooperation Agreement as of December 31, 2018 totaled \$52,000 and were all costs of ANJI. For the year ended December 31, 2018, Cooperation Agreement costs and reimbursement activity of \$52,000 has been shown net and, accordingly, the Cooperation Agreement had no impact on the Consolidated Statements of Operations at December 31, 2018.



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

## 2.FURNITURE AND EQUIPMENT

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

	December 31,	
	2018	2017
Machinery and equipment	\$47	\$221
Furniture and fixtures	4	34
	51	255
Less accumulated depreciation and amortization	(51)	(255)
Total	\$—	\$—

All furniture and equipment are fully depreciated and there was no depreciation or leasehold improvement amortization expenses for the years ended December 31, 2018 and 2017.

**3. INCOME TAXES**

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

	December 31,	
	2018	2017
Accruals and reserves	\$—	\$—
Valuation allowance	—	—
Total current	\$—	\$—
NOL, AMT and general business credit carryforwards	37,607	37,557
Other	114	157
Valuation allowance	(37,721)	(37,714)
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 \$38 million at December 31, 2018 and \$38 million at December 31, 2017. Effective January 1, 2018, the Federal corporate income tax rate has been decreased from 34% to 21%. The effect of this change on deferred taxes and the valuation allowance at December 31, 2017 was approximately \$19 million. The valuation allowance as of December 31, 2018 and 2017 includes approximately \$1.8 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.

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

	Years Ended	
	December	
	31,	
	2018	2017
Provision (benefit) for income taxes		

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Current	\$ (52)	\$ (36)
Deferred	—	\$ —
Income tax provision (benefit)	\$ (52)	\$ (36)

The 2018 and 2017 income tax benefits result from the Australian refundable research and development tax credit as explained in Note 6. Additionally, in 2018 the Company recorded a \$49,000 AMT refundable tax credit, as provided for in the Tax Cuts and Jobs Act.

We have accumulated approximately \$149 million in federal and \$15 million in state net operating loss carryforwards (“NOLs”) and approximately \$5.4 million of research and development and alternative minimum tax credit carryforwards. The federal NOLs expire between 2023 and 2038. The Arizona state NOL’s expire between 2032 and 2038. 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.

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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, 2018 and 2017:

	Years Ended	
	December 31,	
	2018	2017
Income tax provision (benefit) at statutory rate	\$(90)	\$(597 )
State income taxes	(20)	(26 )
Effect of change in federal tax rate	—	19,159
Other	51	437
Change in valuation allowance	7	(19,009)
Net provision (benefit)	\$(52)	\$(36 )

#### 4. 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, 2018, 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.

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 use the Black-Scholes model to determine the total fair value of options to purchase shares of our common stock. No options were granted in 2018 and at December 31, 2018 no options remained available to grant under the Plans.

**Summary**

There was no non-cash stock compensation cost for the year ended December 31, 2018 or 2017. Non-cash stock compensation cost, if any, would be recorded as a general and administrative expense in the Statement of Operations.

No options were exercised in the years ended December 31, 2018 and 2017.

At December 31, 2018, there was no remaining unamortized non-cash stock compensation costs.

In March 2019, the Company filed Post-Effective Amendments to the Form S-8s for our 2005 Equity Incentive Plan and our 2015 Equity Incentive Plan to terminate the effectiveness of the Registration Statements and to remove from registration all securities that remain unsold under the Plans. This action does not affect the terms of the outstanding options but may subject subsequently exercised options to additional resale restrictions or requirements.

A summary of option activity under our stock option plans for the years ended December 31, 2018 and 2017 is as follows:

	2018		2017		Weighted average remaining contractual term (years)
	Number of Options	Weighted average exercise price	Number of Options	Weighted average exercise price	
Options outstanding at the beginning of the year:	3,516,706	\$ 0.34	3,611,706	\$ 0.37	
Granted	-		-	\$ 0.37	
Exercised	-		-		
Expired/Forfeited	(509,706 )	\$ 0.64	(95,000 )	\$ 1.49	
Outstanding at end of year	3,007,000	\$ 0.29	3,516,706	\$ 0.34	4.46
Options exercisable at year-end	3,007,000	\$ 0.29	3,516,706	\$ 0.34	4.46
Options vested and expected to vest at year end	3,007,000	\$ 0.29	3,516,706	\$ 0.34	4.38

The Company had no unvested common stock share awards as of December 31, 2018, or December 31, 2017, and no common stock awards were made in 2018 or 2017.

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, 2018 of \$0.02, stock options exercisable or expected to vest at December 31, 2018, have no intrinsic value.

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2018, on January 30, 2018, the Company entered into the First Amendment to Securities Purchase, Loan and Security Agreement (the "Amendment") with BP Peptides, LLC ("Brookstone"). Brookstone currently owns approximately 34.1% of our outstanding common stock. Under the original Agreement (see Note 10), interest on the Secured Debt was payable quarterly. The Amendment defers the payment of interest until the Secured Debt's maturity, October 15, 2020. In consideration for the deferral, the Company issued a Warrant to Brookstone to purchase up to 6,321,930 shares of the Company's Common Stock with an exercise price of \$.075 per share. The warrant expires October 15, 2025 and provides for quarterly vesting of shares in amounts approximately equal to the amount of quarterly interest payable that would have been payable under the Agreement, converted into shares at \$.075. At December 31, 2018 2,436,811 shares are fully vested and exercisable.

## 5. COMMITMENTS

Rent expense for the years ended December 31, 2018 and 2017, was \$45,000 and \$74,000, 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 February 28, 2020. Effective March 1, 2018 the rentable square feet of space was reduced to 1,379 square feet, with monthly rental payments of approximately \$2,500 plus a proportionate share of building operating expenses and property taxes.

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

In March 2014, LipimetiX Development LLC, (Now LipimetiX Development, Inc. - see Note 8 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. For the tax year ended December 31, 2017 Lipimetix Australia Pty Ltd received a refundable research and development tax credit of AUD\$42,000, and at December 31, 2018 a AUD\$4,000 refundable research and development tax credit has been recorded by Lipimetix Australia Pty Ltd.

## **7. 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.

The Board of Directors of the Company approved a Tax Benefit Preservation Plan (“Benefit Plan”) dated April 18, 2017, between the Company and Computershare. The Benefit Plan and the exercise of rights to purchase Series A Preferred Stock, pursuant to the terms thereof, may delay, defer or prevent a change in control without the approval of the Board. In addition to the anti-takeover effects of the rights granted under the Benefit Plan, the issuance of preferred stock, generally, could have a dilutive effect on our stockholders.

Under the Benefit Plan, each outstanding share of our common stock has attached one preferred stock purchase right. Each share of our common stock subsequently issued prior to the expiration of the Benefit Plan will likewise have attached one right. Under specified circumstances involving an “ownership change,” as defined in Section 382 of the Internal Revenue Code (the “Code”), the right under the Benefit Plan that attaches to each share of our common stock will entitle the holder thereof to purchase 1/100 of a share of our Series A preferred stock for a purchase price of \$5.00 (subject to adjustment), and to receive, upon exercise, shares of our common stock having a value equal to two times the exercise price of the right. The Benefit Plan expires December 31, 2020.

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



On August 3, 2012, we entered into a Contribution Agreement with LipimetiX, LLC to form a joint venture, LipimetiX Development, LLC (“JV”), to develop Apo E mimetic molecules, including AEM-28 and its analogs. In June 2015, the JV converted from a limited liability company to a corporation, LipimetiX Development, Inc. The Company contributed \$6 million, which included \$1 million for 600,000 voting common ownership units (now common stock), representing 60% ownership in the JV, and \$5 million for 5,000,000 non-voting preferred ownership units (now Series A Preferred Stock), which have preferential distribution rights. On March 31, 2016, the Company converted 1,500,000 shares of its preferred stock into 120,000 shares of common stock, increasing its common stock ownership from 60% to 64%. On August 11, 2017, the remaining \$3,500,000 (3,500,000 shares) of Series A preferred stock became convertible, at the Company’s option, into common stock, at the lower of the Series B Preferred Stock Conversion Price, as may be adjusted for certain events, or the price of the next LipimetiX Development, Inc. financing, exceeding \$1,000,000 on independently set valuation and terms. On August 11, 2017, the Company purchased 93,458 shares of LipimetiX Development, Inc.’s Series B-2 Preferred Stock for \$1,000,000 (LipimetiX Development, Inc. incurred \$15,000 in transaction costs as part of the Series B-2 Preferred Stock issuance, which was been shown as a reduction of Additional Paid in Capital on the Consolidated Statements of Changes in Equity and a cash flow provided by financing activities in the Consolidated Statements of Cash Flows at December 31, 2017). As discussed below, the JV Series B-1 and B-2 Preferred Stock issuances, because of the participating and conversion features of the preferred stock, effectively changes the Company’s ownership in the JV to 62.2%. With the Series B-1 and B-2 Preferred Stock on an as-converted basis, and the Company converting its Series A Preferred Stock to common stock, the Company’s ownership would change to 69.75%. The JV 2016 Equity Incentive Plan has 83,480 shares of the JV’s common stock available to grant, of which, at December 31, 2018, options to purchase JV common stock shares totaling 81,479 have been granted and are fully vested. All options were granted with an exercise price of \$1.07, vested 50% on the date of grant and monthly thereafter in equal amounts over a twenty-four-month period and are exercisable for ten years from the date of grant. If all stock available to grant in the JV 2016 Equity Incentive Plan were granted and exercised, and the Series B-1 Preferred Stock Warrants were exercised, the Company’s fully diluted ownership (on an as-converted basis) would be approximately 65.11%. On October 27, 2017 the Board granted Mr. Holliman an option to purchase 14,126 shares of the LipimetiX Development, Inc. Series B-2 Preferred Stock it currently owns, at an exercise price of \$10.70 per share, subject to adjustment and other terms consistent with the Series B-2 Preferred Stock. The option is exercisable for a five-year period from the date of grant. If exercised, this option would reduce the Company’s fully diluted ownership (on an as-converted basis including assumed exercise of other options and warrants) to approximately 64.31%.

LipimetiX, LLC was formed by the principals of Benu BioPharma, Inc. (“Benu”) and UABRF to commercialize UABRF’s intellectual property related to Apo E mimetic molecules, including AEM-28 and analogs. Benu is currently composed of Dennis I. Goldberg, Ph.D. and Eric M. Morrel, Ph.D. LipimetiX, LLC contributed all intellectual property rights for Apo E mimetic molecules it owned and assigned its Exclusive License Agreement between The University of Alabama at Birmingham Research Foundation (“UABRF”) and LipimetiX, LLC, for the UABRF intellectual property related to Apo E mimetic molecules AEM-28 and its analogs to the JV, in return for 400,000 voting common ownership units (now common stock), representing a 40% ownership interest in the JV at formation, and \$378,000 in cash (for certain initial patent-related costs and legal expenses).

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

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

Series B (B-1 and B-2) Preferred Stock is a participating preferred stock. As a participating preferred, the preferred stock will earn a 5% dividend, payable only upon the election by the JV or in liquidation. Prior to the JV common stock holders receiving distributions, the participating preferred stockholders will receive their earned dividends and payback of their original investment. Subsequently, the participating preferred will participate in future distributions on an equal “as-converted” share basis with common stock holders. The Series B Preferred Stock has “as-converted” voting rights and other terms standard to a security of this nature.

The Exclusive License Agreement assigned by LipimetiX, LLC to the JV on formation of the JV, as amended, calls for payment of patent filing, maintenance and other related patent fees, as well as a royalty of 3% on Net Sales of Licensed Products during the Term of the Agreement. The Agreement terminates upon the expiration of all Valid Patent Claims within the Licensed Patents, which are currently estimated to expire between 2019 and 2035. The Agreement, as amended, also calls for annual maintenance payments of \$25,000, various milestone payments of \$50,000 to \$500,000 and minimum royalty payments of \$500,000 to \$1,000,000 per year commencing on January 1 of the first calendar year following the year in which the First Commercial Sale occurs. UABRF will also be paid 5% of Non-Royalty Income received.

Concurrent with entering into the Contribution Agreement and the First Amendment and Consent to Assignment of Exclusive License Agreement between LipimetiX, LLC, UABRF and the Company, the Company and LipimetiX,

LLC entered into a Limited Liability Company Agreement for JV which established a Joint Development Committee (“JDC”) to manage JV development activities. Upon conversion by the JV from a limited liability company to a corporation, the parties entered into a Stockholders Agreement for the JV, and the JDC was replaced by a Board of Directors (JV Board). The JV Board is composed of three members appointed by the non-Company common stock ownership group, three members appointed by the Company and one member appointed by the Series B-1 Preferred Stockholders. Non-development JV decisions, including the issuance of new equity, incurrence of debt, entry into strategic transactions, licenses or development agreements, sales of assets and liquidation, and approval of annual budgets, will be decided by a majority vote of the common and Series B Preferred Stock (voting on an “as -converted” basis) stockholders.

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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. New Management and Accounting Services Agreements were entered into effective June 1, 2016. The monthly management fee in the new Management Agreement was set at \$80,000 and the monthly accounting services fee in the new Accounting Services Agreement was set at \$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, of which \$250,000 was charged to expense in 2016 and \$50,000 was charged to expense in the first quarter of 2017, and Accounting Fees totaling \$60,000, charged to expense in 2016, were paid in 2016. In August 2017 the Accounting Services Agreement monthly fee was increased to \$20,000 and will thereafter be accrued but not payable, until certain levels of joint venture funding are obtained from non-affiliated parties. At December 31, 2018, accounting fees of \$340,000 were earned but unpaid. In August 2017, a Management Fee of \$300,000 was approved by the joint venture's Board of Directors with \$150,000 paid and charged to expense in the third quarter of 2017 and \$150,000 paid and expensed in the first quarter of 2018. Commencing April 2018, a monthly Management Fee of \$50,000 was paid. Commencing January 1, 2019, the monthly Management Fee of \$50,000 will be accrued with payment due on the occurrence of a significant financing event and availability of cash.

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, 2018, losses incurred by the JV exceeded the capital accounts of the JV. The Company has a revolving loan agreement with the joint venture, with the loan due December 31, 2016. In August 2017, the due date of the revolving loan was extended to July 15, 2020, with early payment required upon certain additional funding of the joint venture by non-affiliated parties. Subsequent to June 30,

2017, interest due on the revolving loan will be accrued and payable only upon certain additional funding of the joint venture by non-affiliated parties. Until repayment, the outstanding revolving loan and interest balance is convertible, at the Company's option, into Series B Preferred Stock at the Series B-1 conversion price. Losses incurred by the joint venture in excess of the capital accounts of the joint venture will be allocated to the Company to the extent of the unpaid loan and accrued interest balance. At December 31, 2018, the revolving loan agreement balance, including accrued interest subsequent to June 30, 2017 of \$120,000, was \$1,720,000.

The joint venture incurred net operating income (expenses), prior to the elimination of intercompany transactions, of \$53,000 in 2018 and (\$9,598,000) for the period from August 3, 2012 (inception) to December 31, 2018, of which \$53,000, and (\$7,985,000), 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 December 31, 2018, losses totaling \$667,000 have been allocated to the common stock noncontrolling interests. If the joint venture or Company is unable to obtain additional funding, the ability of the joint venture to continue development of AEM-28 and its analogs would be impaired as would the joint venture's ability to continue operations. If the joint venture does not continue as a going concern, at December 30, 2018, the Company would incur an additional loss of \$667,000 for the joint venture losses allocated to the common stock noncontrolling interests.

## **9. CONVERTIBLE PROMISSORY NOTES**

On December 11, 2015, we entered into a Securities Purchase 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, which provided \$1,000,000 in funding for our operations in the form of Convertible Promissory Notes ("Notes"). The Notes bear interest at 5% and were due April 30, 2017, with the due date subsequently extended to July 14, 2017. The Notes were secured by all intangible and tangible assets of the Company and convertible, either at the election of the Lenders or mandatory on certain future funding events, into either the Company's Common or Preferred Stock. A portion of the funds were advanced to JV to initiate preclinical development activities for our lead commercial drug candidate, AEM-28-14. As described in Note 10 to this Annual Report on Form 10-K, the Convertible Promissory Notes and accrued interest thereon of \$79,000 were paid off on July 14, 2017. Prior to the July 14, 2017 transaction, the Biotechnology Value Fund affiliated entities owned approximately 19% of our outstanding common stock.

## **10. SALE OF COMMON STOCK AND ISSUANCE OF SECURED debt**

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on July 17, 2017, on July 14, 2017, the Company entered into a Securities Purchase, Loan and Security Agreement (the "Agreement") with BP Peptides, LLC ("Brookstone"). The net funds will be used to fund our operations, infuse new capital into our joint venture, LipimetiX Development, Inc. ("JV") (As described in Note 8 to this Annual Report on Form 10-K, in August 2017, the Company used part of the net proceeds to purchase 93,458 shares of LipimetiX Development, Inc.'s Series B-2 Preferred Stock for \$1,000,000.), to continue its development activities, and pay off the Convertible Promissory Notes (as described in Note 9 to this Annual Report on Form 10-K) totaling \$1,000,000, plus \$79,000 in accrued interest.

Pursuant to the Agreement, Brookstone funded an aggregate of \$3,440,000, with net proceeds of approximately \$2,074,000, after paying off the Convertible Promissory Notes and transaction costs, of which \$1,012,500 was for the

purchase of 13,500,000 newly issued shares of our Common Stock, and \$2,427,500 was in the form of a secured loan, due October 15, 2020. On July 14, 2017 Brookstone also purchased 5,041,197 shares of the Company's Common Stock directly from Biotechnology Value Fund affiliated entities, resulting in ownership of 18,541,197 shares of the Company's Common Stock, representing approximately 34.1% of outstanding shares of the Company's Common Stock at December 31, 2018. Transaction costs of \$287,000 have been deferred and will be written off over the life of the secured loan, thirty-nine months from July 14, 2017 to October 20, 2020, on the straight-line basis. Additional transaction costs of \$12,000 were incurred with the Amendment (see Note 11) and will be written off over the period of the date of the Amendment, January 30, 2018, to October 15, 2020. At December 31, 2018 transaction costs of \$134,000 (\$93,000 in 2018 and \$41,000 in the second half of 2017), have been amortized and included in the Consolidated Statements of Operations in Interest and Other Expenses. At December 31, 2018 and December 31, 2017, unamortized transaction costs of \$165,000 and \$246,000, respectively, have been netted against the outstanding Secured Debt balance on the Consolidated Balance Sheets. As discussed in Note 11 below, interest payable on the Secured Debt is now due at loan maturity, October 15, 2020, and, at December 31, 2018 and December 31, 2017, accrued interest of \$213,000 and \$68,000, respectively, has been included in the Secured Debt balance on the Consolidated Balance Sheets. The interest on the secured debt (\$145,000 in 2018 and \$68,000 in the second half of 2017) has been included in the Consolidated Statements of Operations in Interest and other income (expense), net.

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

	December 31, 2018	December 31, 2017
Secured Debt	\$ 2,427	\$ 2,427
Transaction costs	(299 )	(287 )
	\$ 2,128	\$ 2,140
Amortization	134	41
	\$ 2,262	\$ 2,181
Accrued interest	213	68
	\$ 2,475	\$ 2,249

The secured loan bears interest at 6% per annum, with interest payable quarterly (now due at loan maturity see Note 11 below) and is secured by a security interest in all of our assets. As part of the Agreement, the Company and Brookstone entered into a Registration Rights Agreement granting Brookstone certain demand and piggyback registration rights. A provision in the Agreement entered into with Brookstone also requires the Company to nominate two candidates for a director position that have been recommended by Brookstone as long as Brookstone beneficially owns over 20% of the Company's outstanding common stock and to nominate one candidate for a director position that has been recommended by Brookstone as long as Brookstone beneficially owns over 5% but less than 20% of the Company's outstanding common stock.

On April 18, 2017, the Company and Computershare Trust Company, N.A., as Rights Agent (the "Rights Agent") entered into Tax Benefit Preservation Plan Agreement (the "Plan"), dated as of April 18, 2017, between the Company and the Rights Agent, as described in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 19, 2017. The Plan is intended to act as a deterrent to any person (together with all affiliates and associates of such person) acquiring "beneficial ownership" (as defined in the Plan) of 4.99% or more of the outstanding shares of Common Stock without the approval of the Board (an "Acquiring Person"), in an effort to protect against a possible limitation on the Company's ability to use its net operating loss carryforwards. The Board, in accordance with the Plan, granted an Exemption to Brookstone with respect to the share acquisition described above, and Brookstone's acquisition of 5,041,197 shares of the Company's Common Stock from Biotechnology Value Fund affiliated entities, making Brookstone an Exempt Person in respect of such transactions.

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



exceeding \$700,000.

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**11. RELATED PARTY TRANSACTION - DEFERRAL OF SECURED DEBT INTEREST PAYMENTS AND ISSUANCE OF WARRANTS TO PURCHASE SHARES OF THE COMPANY'S COMMON STOCK**

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2018, on January 30, 2018, the Company entered into the First Amendment to Securities Purchase, Loan and Security Agreement (the "Amendment") with BP Peptides, LLC ("Brookstone"). Brookstone currently owns approximately 34.1% of our outstanding common stock. Under the original Agreement (see Note 10 above), interest on the Secured Debt was payable quarterly. The Amendment defers the payment of interest until the Secured Debt's maturity, October 15, 2020. In consideration for the deferral, the Company issued a Warrant to Brookstone to purchase up to 6,321,930 shares of the Company's Common Stock with an exercise price of \$.075 per share. The warrant expires October 15, 2025 and provides for quarterly vesting of shares in amounts approximately equal to the amount of quarterly interest payable that would have been payable under the Agreement, converted into shares at \$. 075. At December 31, 2018 2,436,811 shares are fully vested and exercisable.

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

**Note 12. LIPIMETIX DEVELOPMENT, INC. LICENSE AGREEMENT**

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2018, on May 2, 2018, our JV, LipimetiX Development, Inc., entered into a License Agreement (the "Sub-License") with Anji Pharmaceuticals Inc. ("ANJI") to sublicense, under its Exclusive License Agreement with the UAB Research Foundation, the use of the JV's AEM-28 and analogs intellectual property in the Territory of the People's Republic of China, Taiwan and Hong Kong (the "Territory"). The Sub-License calls for an initial payment of \$2,000,000, payment of a royalty on future Net Sales in the Territory and cash milestone payments based on future clinical/regulatory events. ANJI will perform all development activities allowed under the Sub-License in the Territory at its sole cost and expense. The JV recorded the receipt of the \$2,000,000 payment as revenue in the second quarter of 2018. Transaction costs related to the revenue totaled \$254,000 and consisted of a \$100,000 payment to the UAB Research Foundation, as required by the UAB Research Foundation Exclusive License Agreement, a \$100,000 advisory fee and \$54,000 in legal fees. As described in Note 8 above, at December 31, 2018, JV net losses exceeded the JV capital accounts and all losses were being allocated to the Company. Revenue recorded for the \$2,000,000 payment reduced the amount of JV net losses previously allocated to the Company.

A copy of the UAB Research Foundation Exclusive License Agreement was attached as Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the period ending June 30, 2012 filed with Securities and Exchange Commission ("SEC") on August 10, 2012. A copy of the First Amendment and Consent to Assignment of the Exclusive License Agreement was attached as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the period ending June

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30, 2012 filed with the SEC on August 10, 2012. The Second Amendment to the Exclusive License Agreement was attached as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 30, 2015.

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