

Capstone Therapeutics Corp.
Form 10-K
March 30, 2016

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2015

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements

incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. []

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “small reporting company” in Rule 12b-2 of the Exchange Act. Large accelerated filer Accelerated filer Non-accelerated filer (Do not check if a smaller reporting company) Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based upon the closing sale price of the registrant’s common stock as reported on the OTCQB on June 30, 2015 was approximately \$5,600,000. 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 March 15, 2016, was 40,885,411.

CAPSTONE THERAPEUTICS CORP.

FORM 10-K ANNUAL REPORT

YEAR ENDED DECEMBER 31, 2015

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PART I

Item 1. Business

Overview of the Business

Capstone Therapeutics Corp. (the “Company” or “we”) is a biotechnology company committed to developing a pipeline of novel peptides and other molecules aimed at helping patients with under-served medical conditions. Previously, we were focused on the development and commercialization of two product platforms: AZX100 and Chrysalin (TP508). Since March 2012, we no longer have any interest in or rights to Chrysalin. In 2012 we wound down internal research operations, ceased clinical development of AZX100 in dermal scarring, formerly our principal drug candidate, and moved to a more virtual operating model. In 2014, we terminated the License Agreement for AZX100 intellectual property and returned all interest in and rights to the AZX100 intellectual property to the Licensor (AzTE).

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

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 are randomized, double-blinded, placebo-controlled studies to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of six escalating single doses (Phase 1a in healthy patients with elevated cholesterol) and multiple ascending doses of the three highest doses from Phase 1a (Phase 1b/2a in patients with hypercholesterolemia and 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 has performed limited pre-clinical studies that have identified an analog of AEM-28, referred to as AEM-28-14, and a new formulation, that has the potential of greater efficacy, higher human dose toleration and an extended composition of matter patent life (application filed with the U.S. Patent and Trademark Office in 2015).

The JV and Company intend to explore fundraising, partnering or licensing, to obtain additional funding to continue development activities of AEM-28 and its analogs.

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

The Company, funding permitting, intends to continue limiting its internal research operations to a virtual operating model while monitoring and participating in the management of LipimetiX Development, Inc's AEM-28 and analogs development activities. We intend to maintain the required level of corporate governance and reporting that would be required to comply with Securities and Exchange Commission ("SEC") rules and regulations, except that effective with the filing of this Annual Report on Form 10-K without the opinion of an Independent Public Accountant, we will not be in compliance with SEC Rules and Regulations.

Description of Our Peptide Drug Candidates.

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

Apolipoprotein E is a 299 amino acid protein that plays an important role in lipoprotein metabolism. AEM-28 is a 28 amino acid mimetic of Apo E and AEM-28 and its analogs, including AEM-28-14 is a 28 amino acid mimetic of Apo E (with an aminohexanoic acid group and a phospholipid), and both contain a domain that anchors into a lipoprotein surface while also providing the Apo E receptor binding domain, which allows clearance through the heparan sulfate proteoglycan (HSPG) receptors (Syndecan-1) in the liver. AEM-28 and its analogs, including AEM-28-14, as Apo E mimetics, have the potential to restore the ability of these atherogenic lipoproteins to be cleared from the plasma, completing the reverse cholesterol transport pathway, and thereby reducing cardiovascular risk. This is an important mechanism of action for AEM-28 and its analogs, including AEM-28-14. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia-HoFH), have acute pancreatitis ("AP"), or have hypercholesterolemia, AEM-28 and its analogs may provide a therapeutic solution. Our joint venture has an Exclusive License Agreement with the University of Alabama at Birmingham Research Foundation for AEM-28 and certain of its analogs.

Company History

Prior to November 2003, we developed, manufactured and marketed proprietary, technologically advanced orthopedic products designed to promote the healing of musculoskeletal bone and tissue, with particular emphasis on fracture healing and spine repair. Our product lines, which included bone growth stimulation and fracture fixation devices, are referred to as our "Bone Device Business." In November 2003, we sold our Bone Device Business.

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

In February 2006, we purchased certain assets and assumed certain liabilities of AzERx, Inc. Under the terms of the transaction, we acquired an exclusive license for the core intellectual property relating to AZX100, an anti-fibrotic peptide. In 2014, we terminated the License Agreement with AzTE (Licensor) for the core intellectual property relating to AZX100 and returned all interest in and rights to the AZX100 intellectual property to the Licensor.

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC (now LipimetiX Development, Inc.), (see Note 9 in Notes to Financial Statements included in this Annual Report on Form 10-K for more information) to develop Apo E mimetic peptide molecule AEM-28 and analogs.

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

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

In this Annual Report, references to “we”, “our”, the “Company”, “Capstone Therapeutics”, “Capstone”, and “OrthoLogic” refer to Capstone Therapeutics Corp. References to our joint venture, or the “JV”, refer to LipimetiX Development, Inc. (previously 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 (currently in regulatory approval process). 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 and are currently being marketed: Juxtapid from Aegerion and Kynamro from Sanofi/Genzyme. In the AP indication, the standard of care drugs for reducing triglycerides include fish oil and fibrates, both of which usually take weeks to show an effect. We are currently unaware of any other drugs approved or in development for reducing triglycerides in AP. 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 and its analogs are not currently available for sale and we do not expect them 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, 2015, we had two administrative employees and utilized consultants to perform various administrative, regulatory or research tasks. We have entered into consulting agreements with former employees in an effort to retain their availability to render services if and when needed.

Our research and development for 2015 and 2014 consisted primarily of work with or through our joint venture.

Through our joint venture, LipimetiX Development, Inc. (“JV”), we incurred expenses of \$1.0 million and \$2.4 million relating to AEM-28 and analogs research efforts in 2015 and 2014, respectively. The JV has a development plan to pursue regulatory approval of AEM-28 or an analog (AEM-28-14), as treatment for Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012), AP and other hyperlipidemic indications. The initial development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials had a safety primary endpoint and an efficacy endpoint targeting cholesterol and lipid reduction.

The JV received allowance from regulatory authorities in Australia permitting the JV to proceed with the planned clinical trials. The Phase 1a clinical trial commenced in Australia in April 2014 and the Phase 1b/2a clinical trial commenced in Australia in June 2014. The clinical trials for AEM-28 are randomized, double-blinded, placebo-controlled studies to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of six escalating single doses (Phase 1a in healthy patients with elevated cholesterol) and multiple ascending doses of the three highest doses from Phase 1a (Phase 1b/2a in patients with hypercholesterolemia and 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.

Concurrently with the development activities with AEM-28, the JV has performed limited pre-clinical studies that have identified an analog of AEM-28, referred to as AEM-28-14, and a new formulation, that has the potential of greater efficacy, higher human dose toleration and an extended composition of matter patent life (application filed in 2015). AEM-28-14 has become the JV's lead drug candidate for commercial development.

Manufacturing

Currently, third parties certified under Good Manufacturing Practices manufacture AEM-28 and its analogs for us 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 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 maintain a product liability and 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. Consequently, 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, 2015, we had two full time administrative employees in our operations and utilize consultants to perform a variety of administrative, regulatory or research tasks. We have entered into consulting agreements with various former key employees, but there is no assurance that these persons will be available in the future to the extent their services may be needed. As a research and development business, we believe that the success of our business will depend in part on our ability to identify, attract and retain qualified research personnel, both as employees and as consultants. We face competition from private companies and public institutions for qualified research personnel. None of our employees are represented by a union and we consider our relationship with our employees to be good.

Additional Information about Capstone Therapeutics

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

Our website address is www.capstonethx.com. 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, 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,” “contin

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

• Effect of non-compliance with SEC Rules and Regulations requiring this Annual Report on Form 10-K to include an opinion of an Independent Public Accountant.

• Failure to obtain additional funds to continue operations;

• the impact of the terms or conditions of agreements associated with funds obtained to fund operations;

failure to obtain additional funds required to complete clinical trials and supporting research and production efforts necessary to obtain FDA or comparable foreign agencies approval for product candidates or secure development agreements with pharmaceutical manufacturers;

- the impact of using a virtual operating model;
- unfavorable results of product candidate development efforts;
- unfavorable results of pre-clinical or clinical testing;
- delays in obtaining, or failure to obtain FDA or comparable foreign agencies approvals;
- increased regulation by the FDA or comparable foreign agencies;
- the introduction of competitive products;
- impairment of license, patent or other proprietary rights;
- the impact of present and future joint venture, collaborative or partnering agreements or the lack thereof; and
- failure to successfully implement our drug development strategy for AEM-28 and its analogs.

If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary significantly from what we projected. Any forward-looking statement you read in this Annual Report on Form 10-K reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, business strategy and liquidity. We assume no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Risks Related to Our Business and Industry

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

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

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

We had accumulated deficit balance of \$189 million as of December 31, 2015. Our net loss for the year ended December 31, 2015 was \$2.8 million. We currently have no pharmaceutical products being sold or ready for sale and do not expect to be able to introduce any pharmaceutical products or generate any revenue for at least several years. We expect to incur losses for at least the next several years. Our cash reserves are the primary source of our working capital. These circumstances raise substantial doubt about the Company's ability to continue as a going concern.

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

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

Our JV partners have significant rights as minority-interest stockholders of our JV. Although we own 60% of the outstanding shares of our JV's common stock, the minority stockholders of the JV have the right to appoint a majority of the JV's board of directors.

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

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

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

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

None of our JV's product candidates have been approved for sale. In order to obtain FDA or comparable foreign agency approval to commercialize any product candidate, a New Drug Application (NDA) (or comparable foreign

agency form) must be submitted demonstrating, among other things, that the product candidate is safe and effective for use in humans for each target indication. Our or our JV's regulatory submissions may be delayed, or we or our JV may cancel plans to make submissions for product candidates for many reasons, including unfavorable results from or delays in preclinical or clinical trials and lack of sufficient available funding.

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

the FDA or other health regulatory authorities, or institutional review boards, do not approve a clinical study protocol or place a clinical study on hold;

suitable patients do not enroll in a clinical study in sufficient numbers or at the expected rate, or data is adversely affected by trial conduct or patient drop out;

- patients experience serious adverse events, including adverse side effects of our JV's product candidates;

patients in the placebo or untreated control group exhibit greater than expected improvements or fewer than expected adverse events;

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

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

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

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

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

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

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

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

- we lack of sufficient funds to pay for development costs.

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

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

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

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Several biotechnology and pharmaceutical companies, as well as academic laboratories, universities and other research institutions, are involved in research and/or product development for indications targeted for use by AEM-28 and 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 prospectus.

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

Our success will depend in part on our joint venture’s ability to maintain and enforce patent protection for AEM-28 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 authority that our JV's product candidates are sufficiently safe and effective for a particular indication. We currently rely on third party clinical research organizations and other consultants to assist our JV in designing, administering and assessing the results of those trials and to perform research and development with respect to product candidates. In relying on those third parties, we are dependent upon them to timely and accurately perform their services. If third party organizations do not accurately collect and assess the trial data, our JV may discontinue development of viable product candidates or continue allocating resources to the development and marketing of product candidates that are not efficacious. Either outcome could result in significant financial harm to us.

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

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

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

Our joint venture is managed under contract by Benu BioPharma Inc., which is comprised of three individuals (Dennis I. Goldberg, Ph.D., Phillip M. Friden, 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 \$0.10 during the period of January 1, 2004 through December 31, 2015) and may vary in the future due to a number of factors, including:

- the response by the SEC or the OTCQB Market to our decision not to engage an Independent Public Accountant to audit and express an opinion on our December 31, 2015 Financial Statements;
- 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 often varies widely from day to day. Because of the low trading volume, a relatively small amount of trading may greatly affect the trading price, the trading price may be subject to amplified decreases upon the occurrence of events affecting our business, and investors should not consider an investment in our common stock to be liquid. In addition, the broader stock market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies, and these broad market fluctuations may be even more pronounced for our thinly traded stock.

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

We are authorized to issue 150,000,000 shares of common stock. As of December 31, 2015, there were 40,885,411 shares of common stock issued and outstanding. However, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of options, warrants or additional investment rights. As of December 31, 2015, we had options outstanding to purchase approximately 4,162,706 shares of our common stock, the exercise price of which ranges between \$0.12 per share to \$5.39 per share, warrants outstanding to purchase 46,706 shares of our common stock with an exercise price of \$6.39 per share, and warrants outstanding to purchase 117,423 shares of our common stock with an exercise price of \$1.91 per share, and we have reserved shares of our common stock for issuance in connection with the potential exercise thereof. To the extent additional options are granted and exercised or additional stock is issued, the holders of our common stock will experience further dilution. At December 31, 2015, 280,000 shares remain available to grant under the 2015 Equity Incentive Plan.

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

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

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

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

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

In June 2014, 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 June 24, 2016.

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.

In connection with the Benefit Plan, our Board approved the designation of 1,000,000 shares of Series A Preferred Stock. 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. The Benefit Plan expires June 24, 2016.

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 molecule AEM-28 and its analogs and we contributed \$6 million to the joint venture and at December 31, 2015 we have loaned an additional \$1.5 million to the joint venture. Our cash contribution to the joint venture represents a substantial proportion of our available cash.

The initial funded development plan was focused on the development of treatments using AEM-28 for Homozygous Familial Hypercholesterolemia and Refractory Hypercholesterolemia and extended through Phase 1a and 1b/2a clinical trials, which were completed in the 4th quarter of 2014. Our pre-clinical studies or clinical trials results may not be viewed by potential partners, licensees or acquirers, as successful, and we may not recover our investment.

Even if our development efforts are viewed as successful, a liquidity event, if any, may be insufficient in size to recover our investment.

Our joint venture is unable to continue additional development of AEM-28 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. On October 1, 2014 we amended this lease to extend the term to February 29, 2016 and on February 8, 2016, we extended this lease term to February 28, 2017. We believe the facility is well-maintained and adequate for use through the end of our lease term.

Item 3. Legal Proceedings

In June 2015, we settled our long-pending qui tam lawsuit for a one-time payment of \$50,000. The lawsuit had been filed under seal by Jeffrey J. Bierman, as Relator/Plaintiff, on March 28, 2005 in the United States District Court for the District of Massachusetts against us and substantially all sellers of bone growth stimulation devices during the period 1998-2003. The complaint asserted a variety of claims, including False Claims Act violations. We sold our bone growth stimulation device business in 2003 and first learned of this lawsuit in September 2009.

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.

	2015		2014	
	High	Low	High	Low
First Quarter	\$0.24	\$0.17	\$0.38	\$0.24
Second Quarter	\$0.25	\$0.13	\$0.33	\$0.21
Third Quarter	\$0.24	\$0.15	\$0.39	\$0.21
Fourth Quarter	\$0.17	\$0.10	\$0.27	\$0.19

As of March 15, 2016, 40,885,411 shares of our common stock were outstanding and held by approximately 754 stockholders of record.

Dividends

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Securities Authorized for Issuance under Equity Compensation Plan

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

Item 6. Selected Financial Data

N/A

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

OVERVIEW OF BUSINESS

Company History

Prior to November 2003, we developed, manufactured and marketed proprietary, technologically advanced orthopedic products designed to promote the healing of musculoskeletal bone and tissue, with particular emphasis on fracture healing and spine repair. Our product lines, which included bone growth stimulation and fracture fixation devices, are referred to as our "Bone Device Business." In November 2003, we sold our Bone Device Business.

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

In February 2006, we purchased certain assets and assumed certain liabilities of AzERx, Inc. Under the terms of the transaction, we acquired an exclusive license for the core intellectual property relating to AZX100, an anti-fibrotic peptide. In 2014, we terminated the License Agreement with AzTE (Licensor) for the core intellectual property relating to AZX100 and returned all interest in and rights to the AZX100 intellectual property to the Licensor.

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC (now LipimetiX Development, Inc.), (see Note 9 in Notes to Financial Statements included in this Annual Report on Form 10-K for more information) to develop Apo E mimetic peptide molecule AEM-28 and analogs.

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

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

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

Description of the business

Capstone Therapeutics Corp. (the “Company” or “we”) is a biotechnology company committed to developing a pipeline of novel peptides and other molecules aimed at helping patients with under-served medical conditions. Previously, we were focused on the development and commercialization of two product platforms: AZX100 and Chrysalin (TP508). Since March 2012, we no longer have any interest in or rights to Chrysalin. In 2012 we wound down internal research operations, ceased clinical development of AZX100 in dermal scarring, formerly our principal drug candidate, and moved to a more virtual operating model. In 2014, we terminated the License Agreement for AZX100 intellectual property and returned all interest in and rights to the AZX100 intellectual property to the Licensor (AzTE).

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC (now LipimetiX Development, Inc.), (the “JV”) to develop Apo E mimetic peptide molecule AEM-28 and its analogs. The JV has a development plan to pursue regulatory approval of AEM-28, or an analog, as treatment for Homozygous Familial Hypercholesterolemia

(granted Orphan Drug Designation by FDA in 2012), AP, diabetic dyslipidemia and other hyperlipidemic indications. The initial development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials have 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 are randomized, double-blinded, placebo-controlled studies to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of six escalating single doses (Phase 1a in healthy patients with elevated cholesterol) and multiple ascending doses of the three highest doses from Phase 1a (Phase 1b/2a in patients with hyper-cholesterolemia 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 for AEM-28, the JV has performed limited pre-clinical studies that have identified analogs of AEM-28, including one referred to as AEM-28-14, that have the potential of increased efficacy, higher human dose toleration and an extended composition of matter patent life. The JV has a development plan to pursue regulatory approval and commercialization of AEM-28, or one or more of its analogs, as treatment in orphan (rare disease) indications, including AP and HoFH, and potentially in acute coronary syndrome, peripheral artery disease and metabolic syndrome. HoFH has been designated by the FDA as an orphan indication. We believe that AP may also qualify for orphan indication designation.

The JV and Company are exploring fundraising, partnering or licensing to obtain additional funding to continue development activities of AEM-28 and AEM-28-02.

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

The Company, funding permitting, intends to continue limiting its internal operations to a virtual operating model while monitoring and participating in the management of LipimetiX Development, Inc's AEM-28 and analogs development activities. We intend to maintain the required level of corporate governance and reporting that would be required to comply with Securities and Exchange Commission ("SEC") rules and regulations, except that effective with the filing of this Annual Report on Form 10-K without the opinion or an Independent Public Accountant, we will not be in compliance with SEC Rules and Regulations or OTCQB Market listing requirements.

Description of Our Peptide Drug Candidates.

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

Apolipoprotein E is a 299 amino acid protein that plays an important role in lipoprotein metabolism. AEM-28 is a 28 amino acid mimetic of Apo E and AEM-28-14 (an analog of AEM-28) is a 28 amino acid mimetic of Apo E (with an aminohexanoic acid group and a phospholipid) and both contain a domain that anchors into a lipoprotein surface while also providing the Apo E receptor binding domain, which allows clearance through the heparan sulfate proteoglycan (HSPG) receptors (Syndecan-1) in the liver. AEM-28 and AEM-28-14, as Apo E mimetics, have the potential to restore the ability of these atherogenic lipoproteins to be cleared from the plasma, completing the reverse cholesterol transport pathway, and thereby reducing cardiovascular risk. This is an important mechanism of action for AEM-28 and AEM-28-14. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia-HoFH), have acute pancreatitis, or have hypercholesterolemia, AEM-28 or AEM-28-14 may provide a therapeutic solution. Our joint venture has an Exclusive License Agreement with the University of Alabama at Birmingham Research Foundation for AEM-28 and certain of its analogs.

Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, and expenses in our financial statements and accompanying notes. Management bases its estimates on historical experience and various other assumptions believed to be reasonable. Although these estimates are based on management's best knowledge of current events and actions that may impact the Company in the future, actual results may differ from these estimates and assumptions. Our critical accounting policies are those that affect, or could affect our financial statements materially and involve a significant level of judgment by management.

Income Taxes: Accounting Standards Codification Topic 740 "Income Taxes" requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Changes in valuation allowances from period to period are included in the tax provision in the period of change. In determining whether a valuation allowance is required, we take into account all evidence with regard to the utilization of a deferred tax asset, including past earnings history, expected future earnings, the character and jurisdiction of such earnings, unsettled circumstances that, if unfavorably resolved, would adversely affect utilization of a deferred tax asset, carryback and carryforward periods, and tax strategies that could potentially enhance the likelihood of realization of a deferred asset. We have evaluated the available evidence about future taxable income and other possible sources of realization of deferred tax assets and have established a valuation allowance for all of our deferred tax assets of approximately \$57 million at December 31, 2015.

In March 2014, LipimetiX Development, LLC, now LipimetiX Development, Inc., (see Note 9 in the Financial Statements included in this Annual Report on Form 10-K for more information) formed a wholly-owned Australian subsidiary, Lipimetix Australia Pty Ltd, to conduct Phase 1a and Phase 1b/2a clinical trials in Australia. Currently Australian tax regulations provide for a refundable research and development tax credit equal to 45% of qualified expenditures. Subsequent to the end of its Australian tax years, Lipimetix Australia Pty Ltd intends to submit claims for a refundable research and development tax credit. The transitional Australian tax periods/years granted for Lipimetix Australia Pty Ltd end on June 30, 2014, December 31, 2014 and thereafter December 31 of each succeeding year. For the tax period ended June 30, 2014, Lipimetix Australia Pty Ltd received a refundable research and development tax credit of AUD\$227,000. For the tax period ended December 31, 2014 a refundable research and development tax credit of AUD\$301,000 was received by LipimetiX Australia Pty Ltd. At December 31, 2015, a refundable research and development tax credit of AUD\$189,000 has been accrued, as it is more likely than not, that the recorded refundable research and development tax credit at December 31, 2015 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, 2015, accumulated amortization totaled \$536,000. 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: As discussed in Part I, Item 3 of this Form 10-K under the heading “Legal Proceedings” and in Note 10, “Contingency – Legal Proceedings” in Notes to Financial Statements, 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.

As discussed in Note 9, “Joint Venture for Development of Apo E Mimetic Peptide Molecule AEM-28 and Analogs” in Notes to Financial Statements included in this Annual Report on Form 10-K, the Company entered into a joint venture in which it has contributed \$6,000,000, and the noncontrolling interests have contributed certain patent license rights. Neither the Company nor the noncontrolling interests have an obligation to contribute additional funds to the joint venture or to assume any joint venture liabilities or to provide a guarantee of either joint venture performance or any joint venture liability. The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. Joint venture losses will be recorded on the basis of common ownership equity interests (60% Company / 40% noncontrolling interests) until common ownership equity is reduced to \$0. Subsequent joint venture losses will be allocated to the preferred ownership equity (100% Company). Subsequent to March 31, 2013, all joint venture losses are being allocated to the Company. The Company has a revolving loan agreement with the joint venture to advance the joint venture funds for operations in an amount not to exceed a net (net of expected tax credits or other funds obtained) of \$1,400,000, with the net amount due December 31, 2016. Losses incurred by the joint venture in excess of the capital accounts of the joint venture will be allocated to the Company to the extent of net outstanding advances. At December 31, 2015, outstanding advances on the revolving loan agreement totaled \$1,510,000.

Losses allocated to the noncontrolling interests represent an additional potential loss for the Company as the noncontrolling interests are not obligated to contribute assets to the joint venture to the extent they have a negative capital account and depending on the ultimate outcome of the joint venture, the Company could potentially absorb all losses associated with the joint venture. At December 31, 2015, losses totaling \$667,000 have been allocated to the noncontrolling 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: As discussed in Note 9 to Financial Statements included in this Form 10-K, “Joint Venture for Development of Apo E Mimetic Peptide Molecule AEM-28 and Analogs”, the Company entered into a joint venture in which it has contributed \$6,000,000, and the noncontrolling interests have contributed certain patent license rights. Neither the Company nor the noncontrolling interests have an obligation to contribute additional funds to the joint venture or to assume any joint venture liabilities or to provide a guarantee of either joint venture performance or any joint venture liability. The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. Joint venture losses will be recorded on the basis of common ownership equity interests (60% Company / 40% noncontrolling interests) until common ownership equity is reduced to \$0. Subsequent joint venture losses will be allocated to the preferred ownership equity (100% Company). Subsequent to March 31, 2013, all joint venture losses are being allocated to the Company. The Company has a revolving loan agreement with the joint venture to advance the joint venture funds for operations in an amount not to exceed a net (net of expected tax credits or other funds obtained) of \$1,400,000, with the net amount due December 31, 2016. Losses incurred by the joint venture in excess of the capital accounts of the joint venture will be allocated to the Company to the extent of net outstanding advances.

Recent Accounting Pronouncements

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

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

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

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

Interest and Other Expenses (Income), Net: Interest and Other Expenses (Income), Net, decreased from \$43,000 in 2014 to \$24,000 in 2015 due to the receipt of \$60,000 in 2014 from the conversion of an insurance company, in which we were a policyholder, from mutual to private ownership, with this income offset by a foreign exchange loss of \$120,000 related to our joint ventures' Australian activities. In 2015 the foreign exchange loss was \$28,000.

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

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

Results of Operations Comparing Year Ended December 31, 2014 and 2013.

General and Administrative ("G&A") Expenses: G&A expenses related to our ongoing operations were \$1,453,000 in 2014 compared to \$1,169,000 in 2013. Administration expenses increased primarily due to costs related to the *qui tam* litigation, and investor relations activities.

Research and Development Expenses: Research and development expenses were \$3,071,000 for 2014 compared to \$3,124,000 for 2013. Our research and development expenses in 2014 and 2013 included the operating expenses of LipimetiX Development, LLC, which totaled (net of intercompany transactions) \$2,354,000 for 2014, and \$2,652,000 for 2013. The joint ventures' initial planned research activities have been substantially completed as of December 31, 2014.

Interest and Other Expenses (Income), Net: Interest and Other Expenses (Income), Net, decreased from \$158,000 of Income in 2013 to \$43,000 of Expense in 2014 due to the receipt of \$152,000 in the first quarter of 2013 from the conversion of an insurance company, in which we were a policyholder, from mutual to private ownership versus \$60,000 in 2014. In 2014 this income was offset by a foreign exchange loss of \$120,000 related to our joint ventures' Australian activities.

Income Tax Benefit: Income tax benefit in 2014 consisted of a \$400,000 refundable Australian research and development tax credit, as described in Notes 4 and 7 to the financial statements included in this Annual Report on Form 10-K, related to our joint ventures' Australian clinical trial activities.

Net Loss attributable to Capstone Therapeutics stockholders: We incurred a net loss in 2014 of \$4.2 million compared to a net loss of \$3.9 million in 2013. Net loss includes operations of LipimetiX Development, LLC, which totaled (net of intercompany transactions) \$2,354,000 for 2014, and \$2,652,000 for 2013, net of net loss allocated to noncontrolling interests of \$0 for 2014 and \$193,000 for 2013. The joint ventures' initial planned research activities have been substantially completed as of December 31, 2014.

Liquidity and Capital Resources

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

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC ("JV") to develop Apo E mimetic peptide molecule AEM-28 and its analogs and we contributed \$6.0 million through December 31, 2015 we have loaned an additional \$1,510,000 to the JV. At December 31, 2015, we had cash and cash equivalents of \$1.0 million.

We plan to continue our plan to limit internal operations in a virtual operating model in 2015, however, without additional funding, we will not continue development of AEM-28 and its analogs past completion of the limited projects currently under way. We are exploring strategic options for both the Company and our joint venture. Lack of additional funding within the next 12 months, would impair our ability to continue our current operations and our ability to continue as a going concern..

Funding permitting, our planned operations in 2015 consist of monitoring and participating in the management of LipimetiX Development LLC's AEM-28 and its analogs 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 LipimetiX Development, Inc. operations and obtaining additional funding.

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

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

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

Item 8. Financial Statements and Supplementary Data

Consolidated balance sheets as of December 31, 2015 and December 31, 2014, consolidated statements of operations, changes in equity and cash flows for each of the years in the two-year period ended December 31, 2015, 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, 2015.

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, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

INFORMATION CONCERNING DIRECTORS

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

John M. Holliman, III

John M. Holliman III, 62, has served as Executive Chairman and Principal Executive Officer of the Company since April 2006 and has served as a director of the Company since September 1987 and as Chairman of the Board of Directors since August 1997. Since February 1993 he has been a general partner of entities which are the general partners of Valley Ventures, LP (formerly known as Arizona Growth Partners, LP), Valley Ventures II, LP, Valley Ventures III, LP, Valley Ventures III Annex, LP, all of which are venture capital funds that invest principally in life science companies.

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

Eric W. Fangmann (1)

Eric W. Fangmann, age 46, has served as a director of the Company since June 2014. On March 15, 2016, Mr. Fangmann resigned from the Board of Directors. Mr. Fangmann has been the Chief Financial Officer for Lloyd I. Miller, III, since 2011. Mr. Fangmann is also the Acting President and Acting Chief Financial Officer for Pharmos

Corporation, a pharmaceutical company, since 2012. Mr. Fangmann was previously an independent accounting and finance consultant who was principally engaged by public and private entities to assist in independent analysis and other projects. Mr. Fangmann was appointed by the Board of Directors of Synergy Brands Inc. in 2011 as its chief financial officer and treasurer, and was appointed as officer and/or director of certain of its subsidiaries, to serve in such capacities on an interim basis in connection with certain filings under Chapter 7 of the U.S. bankruptcy code. From 2005 to 2010, Mr. Fangmann served as Executive Vice President Technology of Frontera Investment, Inc., a publicly held cash and loan company. Prior to that, Mr. Fangmann has served principally in senior management accounting and finance functions for both public and private entities such as The Upper Deck Company, LLC, PriceSmart, Inc. and Teletrac, Inc. From 1992 to 1996, Mr. Fangmann worked in the audit division of Arthur Andersen. Mr. Fangmann also serves on the board of directors of Alliance Semiconductor and Global Agora, LLC. Mr. Fangmann holds a B.S. in Accountancy - Cum Laude from the University of Missouri, Columbia, Missouri.

Mr. Fangmann was introduced and recommended to the Board as a nominee for director by Lloyd I. Miller, III, a significant shareholder. The Board believes Mr. Fangmann's diverse financial experience brings important experience to the Board and qualifies him to serve on our Board.

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

Fredric J. Feldman, Ph.D., 75, 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., 76, has served as a director of the Company since September 1987. In 1982, Mr. Howse founded Cable, Howse and Ragen, investment banking and stock brokerage firm, subsequently known as Ragen MacKenzie. In 1977, Mr. Howse co-founded Cable & Howse Ventures, an early stage venture capital firm focused on technology. In 1976, he served as Vice President, Corporate Finance, for Foster & Marshall, a northwest stock brokerage firm. In 1974 he was the Chief Financial Officer of Seattle Stevedore Company and the Miller Produce Company. Mr. Howse has served as a corporate director and advisor to various public, private and non-profit enterprises. He served on the board of the National Venture Capital Association and is past President of the Stanford Business School Alumni Association. He currently serves on the boards of directors of Formotus, Inc., BeneSol Corporation, Stella Therapeutics, Inc. and not-for-profit, Junior Achievement of Washington. Mr. Howse holds a BS in Engineering from Stanford University and an MBA from Stanford Graduate School of Business.

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

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Corporate Governance/Nominating Committee

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

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

Executive Officers

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

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

<u>Name</u>	<u>Age</u>	<u>Title</u>
John M. Holliman, III	62	Executive Chairman and Principal Executive Officer
Randolph C. Steer, MD, Ph.D.	66	Consultant
Les M. Taeger	65	Senior Vice President, Chief Financial Officer and Principal Financial and Accounting Officer

John M. Holliman, III, became Executive Chairman and Principal Executive Officer of the Company on April 5, 2006 and has served as a director of the Company since September 1987 and as Chairman of the Board of Directors since August 1997. Since February 1993 he has been a general partner of entities, which are the general partners of Valley Ventures, LP (formerly known as Arizona Growth Partners, LP), Valley Ventures II, LP, Valley Ventures III Annex, LP, all of which are venture capital funds that invest principally in life science companies.

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

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

Corporate Governance and Code of ethics

The Company’s code of ethics applies to all of its employees and has particular sections that apply only to its principal executive officer and senior financial officers. The Company has posted the text of its code of ethics on its website (www.capstonethx.com), 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, 2015.

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 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	Non-Equity Incentive Plan Compensation	Nonqualified		Total
			Awards		Deferred Compensation	All Other Compensation	
(a)	(\$)	(\$)	(\$)	(e)	Earnings	(\$)	(\$)
(b)	(c)	(d)	(f)	(g)	(h)	(i)	(j)
Fredric J. Feldman, Ph.D.	24,000	18,000	-	-	-	-	42,000

Elwood D. Howse, Jr.	24,000	18,000 -	-	-	42,000
Eric W. Fangmann	24,000	18,000 -	-	-	42,000

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

During the year ended December 31, 2015, the Company paid non-executive directors Board Fees of \$6,000 per quarter. All directors are eligible for a grant of non-qualified stock options pursuant to the Company's 2005 Equity Incentive Plan. The Company granted to each non-executive director (Fangmann, Feldman, Howse) non-qualified options to acquire 50,000 shares at an exercise price of \$0.22 per share on January 2, 2015 (fair value of \$8,000); 10,000 shares at an exercise price of \$0.17 per share on April 10, 2015 (fair value of \$1,000), and 50,000 shares at an exercise price of \$0.25 on June 19, 2015 (fair value \$9,000). These options vested immediately and were granted at the closing market price on the date of grant. All options have been granted with ten-year terms.

Director Outstanding Equity Awards at Fiscal Year-End

Name	Option Awards		Equity Incentive Plan Awards:	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Number of Securities Underlying Unexercised Unearned Options (#)	Options Exercise Price (\$) Option Expiration Date
John M. Holliman, III	200,000			1.75 5/12/2016
	50,000			1.02 2/21/2018
	125,000			0.45 2/3/2019
	100,000			0.82 2/4/2020
	25,000			0.70 10/30/2018
	65,000			0.17 5/18/2022
	65,000			0.16 8/9/2022
	51,000			0.21 2/28/2023
	22,000			0.30 2/6/2024
	50,000			0.17 4/10/2025
*	150,000	50,000		0.25 6/19/2025
	100,000			0.12 12/18/2025
Eric W. Fangmann	50,000			0.24 6/12/2024
Various directors:				
(1) (2) (3)	10,000			4.90 1/2/2016
(1) (2) (3)	25,000			1.75 5/12/2016
(1) (2) (3)	10,000			1.43 1/1/2017
(1) (2) (3)	10,000			1.35 1/1/2018
(1) (3)	25,000			0.70 10/30/2018
(1) (2) (3)	10,000			0.42 1/1/2019
(1) (2) (3)	10,000			0.72 1/1/2020
(1)(2)(3)	10,000			0.58 1/1/2021
(1) (2) (3)	10,000			0.26 1/1/2022
(1)				
(2)	35,000			0.17 5/18/2022
(1) (2)	42,500			0.16 8/9/2022
(1) (2) (3)	10,000			0.17 1/1/2023
(1) (3)	27,000			0.21 2/28/2023
(1)(2)(3)	10,000			0.26 1/1/2024
(1)(3)	12,000			0.30 2/6/2024
(1)(2)(3)(4)	50,000			0.22 1/2/2025
(1)(3)(4)	10,000			0.17 4/10/2025
(1)(2)(3)(4)	50,000			0.25 6/19/2025
Feldman, Fred (1)				
Holliman, John (2)				
Howse, Elwood (3)				

Fangmann, Eric (4)

* Vest in
2016
All other directors options were fully vested on
12/31/2015

EXECUTIVE COMPENSATION

The Compensation Committee's Conclusion

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

Board Approval

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

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

Officer and Key Consultant Compensation

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

In 2015, to conserve the cash resources of the Company, Mr. Holliman received consulting cash compensation of \$54,000 and Dr. Steer received consulting cash compensation of \$63,000. In 2016, consulting cash compensation for Mr. Holliman and Dr. Steer will be at a rate lower than 2015, until additional funding is received by the Company. Additionally, all other employees and consultants cash compensation has been reduce in 2016, until additional funding is received by the Company.

Equity-Based Compensation

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

Stock Option Grants

In 2015, the Company granted options to employees to purchase 880,000 shares of the Company's Common Stock with the exercise price determined by the closing market price on the date of grant (\$0.12 to \$0.25) and an aggregate grant date fair value of \$137,000. These grants included grants to the named executives (Holliman 450,000 shares, Steer 190,000 shares and Taeger 190,000 shares).

Common Stock Awards

The Company did not grant any common stock awards in 2015.

Fringe Benefits, Perquisites and Retirement Benefits.

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

Joint Venture Bonus Plan

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

The Plan provides for a bonus pool, shared 40% by Mr. Holliman, 40% by Dr. Steer and 20% by Mr. Taeger, of 2.5% of the cash or in-kind distributions from the JV to the Company after the Company has received the return of its initial \$6,000,000 investment. The individuals’ interest in the bonus pool vested 50% upon Board approval of the Plan (August 9, 2012) and vested 50% upon the presentation by the JV to its Members of quantitative/qualitative safety and efficacy results from all protocol-designated endpoints of the AEM-28 Phase 1b/2a clinical trial. The bonuses are fully vested at December 31, 2015; however, no amounts have been earned as of December 31, 2015.

Summary Compensation Table

The following table sets forth, with respect to the years ended December 31, 2015, 2014 and 2013, 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	Deferred Earnings	All Other Compensation	Total
		(\$)	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	
John M. Holliman, III Executive Chairman (Principal Executive Officer)	2015	54,000	-	-	67,000	-	-	-	16,000	137,000
	2014	100,000	-	-	7,000	-	-	-	31,000(1)	138,000
	2013	100,000	-	-	7,000	-	-	-	41,000(1)	148,000
Randolph C. Steer, MD, Ph.D., Consultant	2015	63,000	-	-	31,000	-	-	-	-	94,000