Capstone Therapeutics Corp.
Form 10-K
March 16, 2015

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, 2014

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

1275 West Washington Street, Suite 104, Tempe, Arizona 85281
(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. o Yes No x

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

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. x Yes o 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). x Yes o 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. o

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 o Accelerated filer o Non-accelerated filer o (Do not check if a smaller reporting company) Smaller Reporting Company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).
o Yes x 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, 2014 was approximately $7,200,000. Shares of common stock held by each officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily conclusive.

Documents incorporated by reference: None

The number of outstanding shares of the registrant’s common stock on February 28, 2015 was 40,885,411.

CAPSTONE THERAPEUTICS CORP.
FORM 10-K ANNUAL REPORT
YEAR ENDED DECEMBER 31, 2014

TABLE OF CONTENTS

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 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, (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) and other hyperlipidemic indications. The initial development plan extended through Phase 1a and 1b/2a clinical trials and was completed in the fourth quarter of 2014. The clinical trials have a safety primary endpoint and an efficacy endpoint targeting reduction of cholesterol and triglycerides.

The JV received allowance from regulatory authorities in Australia permitting the JV to proceed with the planned clinical trials. The Phase 1a clinical trial commenced in Australia in April 2014 and the Phase 1b/2a clinical trial commenced in Australia in June 2014. The clinical trials for AEM-28 are randomized, double-blinded, placebo-controlled studies to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of six escalating single doses (Phase 1a in healthy patients with elevated cholesterol) and multiple ascending doses of the three highest doses from Phase 1a (Phase 1b/2a in patients with hypercholesterolemia and 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-28-02, and a new phospholipid formulation, that has the potential of equivalent efficacy, higher human dose toleration and an extended composition of matter patent life (application filed with the U.S. Patent and Trademark Office in 2014).

The JV and Company intend to explore 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. 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-28-02 for treatment of acute coronary syndrome and other indications.

The Company intends to limit its internal operations to a virtual operating model while continuing monitoring and participating in the management of LipimetiX Development, LLC's AEM-28 and analogs development activities and maintaining the required level of corporate governance and reporting required to comply with Securities and

Exchange Commission rules and regulations.

Description of Our Peptide Drug Candidates.

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

Apolipoprotein E is a 299 amino acid protein that plays an important role in lipoprotein metabolism. AEM-28 is a 28 amino acid mimetic of Apo E and AEM-28-02 (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-28-02, 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-28-02. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia-HoFH), or have hypercholesterolemia, AEM-28 or AEM-28-02 may provide a therapeutic solution. Our joint venture has an Exclusive License Agreement with The University of Alabama 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, (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" ref 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, LLC.

5

Competition

The biopharmaceutical industry is characterized by intense competition and confidentiality. We may not be aware of the other biotechnology, pharmaceutical companies or public institutions that are developing pharmaceuticals or devices that 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.

AEM-28 and Analogs

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.

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, we currently have no 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, 2014, we had two administrative employees and utilized consultants to perform various administrative, regulatory or research tasks. We have entered into consulting agreements with several former employees in an effort to retain their availability to render services if and when needed.

Our research and development for 2014 and 2013 consisted primarily of work with or through our joint venture.

Through our joint venture, LipimetiX Development, LLC (“JV”), we incurred expenses of $2.4 million and $2.7 million relating to AEM-28 and analogs research efforts in 2014 and 2013, respectively. 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) 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 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-28-02, and a new phospholipid formulation, that has the

potential of equivalent efficacy, higher human dose toleration and an extended composition of matter patent life (application filed in 2014).

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 based on an infusion formulation.

Patents, Licenses and Proprietary Rights

The JV we entered into on August 3, 2012, LipimetiX Development, LLC, 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 2034. 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.

Capstone Therapeutics is a registered United States domestic trademark of Capstone Therapeutics Corp.

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, 2014, 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," "continu of these terms or other comparable terminology. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond our control and which could materially affect actual results, levels of activity, performance or achievements. Factors that may cause actual results to differ materially from current expectations, which we describe in more detail in this section titled "Risks," include, but are not limited to:

- the impact of our actions to preserve cash, including the reduction from eighteen employees to two employees and additional steps taken towards a virtual operating model;
- unfavorable results of product candidate development efforts, including through our joint venture;
- unfavorable results of pre-clinical or clinical testing, including through our joint venture;
- delays in obtaining, or failure to obtain FDA or comparable foreign agencies approvals;
- increased regulation by the FDA or comparable foreign agencies;
- the introduction of competitive products;
- impairment of license, patent or other proprietary rights;
- the impact of present and future joint venture, collaborative or partnering agreements or the lack thereof;
- failure to successfully implement our drug development strategy for AEM-28 and its analogs;

- 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;
- effect of the ongoing qui tam litigation on our stock price, liquidity, and our ability to execute corporate or other transactions, or our ability to continue operations; and
- Qui tam litigation costs or any resulting judgment could exceed our available resources, and we may be forced to liquidate before fully exploring the value that could be realized from our joint venture's development activities.

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

We are a defendant in a qui tam, Federal False Claims Act lawsuit that, if unsuccessfully resolved, could materially and adversely impact our business.

In September 2009, we were served with a qui tam complaint, filed in the U.S. District Court for the District of Massachusetts, alleging violations of the Federal False Claims Act in connection with our sales of bone growth stimulation devices prior to our sale of that business in November 2003. See Item 3, Legal Proceedings, below, for a discussion of this lawsuit. On December 8, 2010, the court denied our motion to dismiss and we filed our answer on January 28, 2011. No trial date has been set and discovery in the case is now open.

We believe that our billing practices related to our sale of bone growth stimulation devices complied with applicable laws and that we have meritorious defenses to the complaint. However, because of the many questions of law and fact that may arise, we cannot at this time predict the outcome of the litigation or its impact on our business, liquidity or financial condition. The Relator seeks damages which, if awarded, could include a statutory penalty for each bone stimulation device sold during the relevant period and which, in the aggregate, could exceed the financial resources of the Company. If we are unable to successfully defend or otherwise dispose of this litigation, and the Relator is awarded the damages sought, we would not be able to continue our business as it is presently conducted.

The pendency of this claim may impede or have a material adverse affect on our ability to effect a dissolution, issue a dividend or enter into a strategic transaction.

We are a biopharmaceutical company with no revenue generating operations and high investment costs.

We expect to incur losses for a number of years. Our current level of funds is not sufficient to support all research expenses to achieve commercialization of any of our product candidates. In November 2003, we sold all of our revenue generating operations. We are now focused on developing and testing the product candidates of AEM-28 and its analogs (through our joint venture, LipimetiX Development, LLC) and have allocated most of our resources to bringing these product candidates to the market, either through clinical trials or partnering efforts. We currently have no pharmaceutical products being sold or ready for sale and do not expect to be able to introduce any pharmaceutical products for at least several years. As a result of our significant research and development, clinical development, regulatory compliance and general and administrative expenses and the lack of any products to generate revenue, we expect to incur losses for at least the next several years and expect that our losses will increase if we expand our

research and development activities and incur significant expenses for clinical trials. Our cash reserves are the primary source of our working capital. To complete the clinical trials and supporting research and production efforts necessary to obtain FDA or comparable foreign agencies' approval for AEM-28 and its analogs product candidates would require us to seek other sources of capital. New sources of funds, including raising capital through the sales of securities, joint venture or other forms of joint development arrangements, sales of developments rights, or licensing agreements, may not be available or may only be available at terms that would have a material adverse impact on our existing stockholders' interests.

We may not receive any revenue from our product candidates until we receive regulatory approval and begin commercialization of our product candidates. We cannot predict when that will occur or if it will occur.

We caution that our future cash expenditure levels are difficult to forecast because the forecast is based on assumptions about the level of future operations, including the number of research projects we pursue, the pace at which we pursue them, the quality of the data collected and the requests of the FDA or comparable foreign agencies to expand, narrow or conduct additional clinical trials and analyze data. Changes in any of these assumptions can change significantly our estimated cash expenditure levels.

Our AEM-28 and analogs product candidates have reached various stages of development but may not be successfully developed or commercialized.

If we fail to commercialize our product candidates, we will not be able to generate revenue. We currently do not sell any products. Our product candidates have reached the following stages of development:

AEM-28:

- Completed Phase 1 and Phase 1b/2a human clinical trials

AEM-28-02:

- Pre-clinical studies

We are subject to the risk that:

- the FDA or comparable foreign agencies finds some or all of our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;
- we are unable to get some or all of our product candidates to market in a timely manner;
- we are not able to produce our product candidates in commercial quantities at reasonable costs;
- our products undergo post-market evaluations resulting in marketing restrictions or withdrawal of our products; or
- the patients, insurance and/or physician community does not accept our products.

In addition, our product development programs may be curtailed, redirected or eliminated at any time for many reasons, including:

- adverse or ambiguous results;
- undesirable side effects which delay or extend the trials;
- inability to locate, recruit, qualify and retain a sufficient number of patients for our trials;
- regulatory delays or other regulatory actions;
- difficulties in obtaining sufficient quantities of the particular product candidate or any other components needed for our pre-clinical testing or clinical trials;
- change in the focus of our development efforts;
- re-evaluation of our clinical development strategy; and

- lack of sufficient funds to pay for development costs.

We cannot predict whether we will successfully develop and commercialize any of our product candidates. If we fail to do so, we will not be able to generate revenue.

If one of our product candidates reveals safety or fundamental efficacy issues in clinical trials, it could adversely impact the development path for our other current product candidates for that peptide.

Should the results of pre-clinical studies or human clinical trials show negative safety or efficacy data, it may adversely impact the development of our product candidates, or partnering opportunities for our product candidates.

If we cannot protect the AEM-28 and its analogs patents, or our intellectual property generally, our ability to develop and commercialize our products will be severely limited.

Our success will depend in part on our 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 we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products would then be diminished.

AEM-28 and its analogs are patented and 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, whether to enforce our rights to use our or our licensors' patents or to defend against allegations that we infringe third party rights, 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 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 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 ability to operate and commercialize products without infringing on the patents or proprietary rights of others.

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

11

- pay substantial damages;
- stop using our 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 us, or may not be available on acceptable terms. If we or our licensors or suppliers are sued for infringement, we could encounter substantial delays in, or be prohibited from, developing, manufacturing and commercializing our product candidates.

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

As a small company our success depends on the continuing contributions of our management team and scientific personnel, and maintaining relationships with the network of medical and academic centers in the United States and centers that conduct our clinical trials. On October 31, 2011, we reduced our staff to four employees and as of December 31, 2014, we only have 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 LipimetiX Development, LLC joint venture is managed 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.). Should any of these individuals not continue to provide services to the joint venture, it could have a material adverse effect on the joint venture’s ability or cost to develop AEM-28 and its analogs.

Our reliance on outside suppliers and consultants could have a material effect on our ability to perform research or clinical trials.

We rely on outside suppliers and consultants for the manufacture of AEM-28 and its analogs, and technical assistance in our research and development efforts. The inability of our suppliers to meet our production quality requirements in a timely manner, or the lack of availability of experienced consultants to assist in our research and development efforts could have a material adverse effect on our ability to perform research or clinical trials.

We face an inherent risk of liability in the event that the use or misuse of our products results in personal injury or death.

The use of our product candidates in clinical trials may expose us 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. In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, 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.

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, LLC may not be recovered.

12

On August 3, 2012, we entered into a joint venture with LipimetiX, LLC 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, 2014 we have loaned an additional $500,000 to the joint venture. Our cash contribution to the joint venture represents a substantial proportion of our available cash.

The initial funded development plan will be focused on the development of treatments 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.