

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

Capstone Therapeutics Corp.  
Form 10-K  
March 27, 2014

U.S. SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2013

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

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

Commission file number: 0-21214

CAPSTONE THERAPEUTICS CORP.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or  
organization)

86-0585310  
(IRS Employer Identification No.)

1275 West Washington Street, Suite 104, Tempe, Arizona 85281  
(Address of principal executive offices)  
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  
(Title of Class)

OTCQB  
(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

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

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 [x]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).  
[ ] 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, 2013 was approximately \$5,100,000. 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, 2014 was 40,885,411.

CAPSTONE THERAPEUTICS CORP.  
 FORM 10-K ANNUAL REPORT  
 YEAR ENDED DECEMBER 31, 2013

TABLE OF CONTENTS

	PAGE
<u>PART I</u>	<u>4</u>
<u>Item 1. Business</u>	<u>4</u>
<u>Item 1A. Risk Factors</u>	<u>9</u>
<u>Item 1B. Unresolved Staff Comments</u>	<u>18</u>
<u>Item 2. Properties</u>	<u>19</u>
<u>Item 3. Legal Proceedings</u>	<u>19</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>19</u>
<u>PART II</u>	<u>20</u>
<u>Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>20</u>
<u>Item 6. Selected Financial Data</u>	<u>20</u>
<u>Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>23</u>
<u>Item 7A. Quantitative and Qualitative Disclosures about Market Risk</u>	<u>30</u>
<u>Item 8. Financial Statements and Supplementary Data</u>	<u>30</u>
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	<u>30</u>
<u>Item 9A. Controls and Procedures</u>	<u>30</u>
<u>Item 9B. Other Information</u>	<u>31</u>
<u>PART III</u>	<u>31</u>
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	<u>31</u>
<u>Item 11. Executive Compensation</u>	<u>34</u>
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>42</u>
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	<u>43</u>
<u>Item 14. Principal Accountant Fees and Services</u>	<u>43</u>
<u>PART IV</u>	<u>44</u>
<u>Item 15. Exhibits and Financial Statement Schedules</u>	<u>44</u>
<u>SIGNATURES</u>	<u>S-1</u>
<u>EXHIBIT INDEX</u>	<u>E-1</u>
<u>FINANCIAL STATEMENTS</u>	<u>F-1</u>

PART I

Item 1. Business

Overview of the Business

Capstone Therapeutics Corp. 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). We no longer have any interest in or rights to Chrysalin. 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.

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. Certain manufacturing and regulatory activities related to AZX100 that are required either from a statutory perspective or for reporting purposes, will continue. We are also performing limited pre-clinical studies with AZX100 in fibrosis. We are currently seeking development partnering or licensing opportunities for AZX100 in dermal scarring, pulmonary fibrosis and peridural fibrosis.

The JV has a development plan to pursue regulatory approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012). The initial development plan will extend through Phase 1a and 1b/2a clinical trials and is expected to be completed in the fourth quarter of 2014. The clinical trials will have a safety primary endpoint and an efficacy endpoint targeting reduction of LDL and non-HDL cholesterol.

Regulatory filings have been made by the JV in both Canada and Australia seeking allowance to commence the proposed clinical trials. The proposed clinical trials for AEM-28 are randomized, double-blinded, placebo-controlled studies to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending doses (Phase 1a in healthy patients) and multiple ascending doses (Phase 1b/2a in patients with Refractory Hypercholesterolemia). It is expected that the Phase 1a clinical trial will consist of 36 patients and the Phase 1b/2a will consist of 15 patients. The JV anticipates receiving allowance from regulatory authorities in Australia permitting the JV to proceed with the planned clinical trials. Based on this anticipated allowance, the JV has elected to pursue clinical trials in Australia. The JV will continue to work with Canadian regulatory authorities, and may, conditions permitting, conduct future clinical trials in Canada, the USA and other regulatory jurisdictions. The JV may also fund research or studies to investigate Apo E mimetic molecules, including AEM-28 and analogs, for treatment of acute coronary syndrome. For a description of the JV, please refer to Note 10 to our financial statements included in this Form 10-K.

The Company intends to limit its internal operations to a virtual operating model while continuing our development partnering efforts for AZX100, investigating pre-clinical, clinical or other strategic options for AZX100, 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 Prior and Current Peptide Drug Candidates.

Apo E Mimetic Peptide Molecule – AEM-28

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 that contains 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, as an Apo E mimetic, has 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. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia, HoFH), or have Severe Refractory Hypercholesterolemia, AEM-28 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. The JV has performed pre-clinical studies with AEM-28.

## AZX100

AZX100 is a novel synthetic 24-amino acid peptide and is believed to have smooth muscle relaxation and anti-fibrotic properties. AZX100 has been evaluated for medically and commercially significant applications, such as prevention of hypertrophic and keloid scarring and treatment of pulmonary and peridural fibrosis. We filed an IND for a dermal scarring indication in 2007 and completed Phase 1a and Phase 1b safety clinical trials in dermal scarring in 2008. We commenced Phase 2 clinical trials in dermal scarring following shoulder surgery and keloid scar revision in the first quarter of 2009. During 2010 we completed and reported results for our clinical trials in keloid scar revision and substantially completed our Phase 2 clinical trial in dermal scarring following shoulder surgery. We completed and reported our Phase 2 clinical trial in dermal scarring following shoulder surgery in 2011. We have an exclusive worldwide license to AZX100. In the first quarter of 2012 we ceased clinical development of AZX100 in dermal scarring, formerly our principal drug candidate. We are currently performing limited pre-clinical studies in fibrosis.

## Company History

Prior to November 26, 2003, we developed, manufactured and marketed proprietary, technologically advanced orthopedic products designed to promote the healing of musculoskeletal bone and tissue, with particular emphasis on fracture healing and spine repair. Our product lines included bone growth stimulation and fracture fixation devices are referred to as our “Bone Device Business.”

On November 26, 2003, we sold our Bone Device Business. Our principal business remains focused on under-served medical conditions, although through biopharmaceutical approaches rather than through the use of medical devices.

On August 5, 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. We became a development stage entity commensurate with the acquisition. Subsequently, our efforts were focused on research and development of Chrysalin with the goal of commercializing our product candidates. (In March 2012, we returned all rights to the Chrysalin intellectual property and no longer have any interest in, or rights to, Chrysalin.

On February 27, 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.

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, (see Note 10 to the financial statements included in this Annual Report) to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

Our development activities represent a single operating segment as they shared the same product development path and utilized the same Company resources. As a result, we determined that it is appropriate to reflect our operations as one reportable segment. Through December 31, 2013, we have incurred \$154 million in net losses as a development stage company.

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 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 refer to LipimetiX Development, LLC.

## 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 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.

## AZX100

### Dermal Scarring

#### Approved

We are not aware of any regulated pharmacologic treatment specifically approved for dermal, hypertrophic or keloid scar reduction. Keloid scars are often excised and treated with pressure, radiation, corticosteroids or other agents, with variable results.

#### In Development

Under an agreement with Isis Pharmaceuticals, Excaliard Pharmaceuticals was developing EXC001, an antisense oligonucleotide, to inhibit expression of connective tissue growth factor (CTGF) to interrupt the process of fibrosis and scarring. Excaliard announced in January 2011 positive six-month efficacy results from small Phase 2 proof-of-concept clinical trials in 1) fine line scars from elective abdominoplasty, and 2) revision of hypertrophic scars from prior breast surgery. Excaliard Pharmaceuticals has been acquired by Pfizer, Inc., who is currently conducting a Phase 2 clinical trial with EXC001.

### Pulmonary Fibrosis

Several investigative agents are in Phase 3 clinical trials, including pirfenidone (Pirespa – Intermune), which is approved for sale in Canada, Japan and the European Union.

## AEM-28

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

AZX100 and AEM-28 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.

6

---

## Research and Development

At December 31, 2013, 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 AZX100 in 2013 and 2012 consisted primarily of management of outsourced pre-clinical fibrosis studies.

We incurred expenses of \$0.5 million and \$1.3 million, in 2013 and 2012, respectively, related to research (Pre-clinical, Clinical, Chemical Materials and Controls, Regulatory and Quality Assurance departments) efforts on AZX100.

Through our joint venture, LipimetiX Development, LLC (“JV”), we incurred expenses of \$2.7 million and \$1.1 million relating to AEM-28 research efforts in 2013 and 2012, respectively. The JV has a development plan to pursue regulatory approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012). The initial development plan will extend through Phase 1a and 1b/2a clinical trials and is expected to be completed in the fourth quarter of 2014. The clinical trials will have a safety primary endpoint and an efficacy endpoint targeting reduction of LDL and non-HDL cholesterol.

Regulatory filings have been made by the JV in both Canada and Australia seeking allowance to commence the proposed clinical trials. The proposed clinical trials for AEM-28 are randomized, double-blinded, placebo-controlled studies to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending doses (Phase 1a in healthy patients) and multiple ascending doses (Phase 1b/2a in patients with Refractory Hypercholesterolemia). It is expected that the Phase 1a clinical trial will consist of 36 patients and the Phase 1b/2a will consist of 15 patients. The JV anticipates receiving allowance from regulatory authorities in Australia permitting the JV to proceed with the planned clinical trials. Based on this anticipated allowance, the JV has elected to pursue clinical trials in Australia. The JV will continue to work with Canadian regulatory authorities, and may, conditions permitting, conduct future clinical trials in Canada, the USA and other regulatory jurisdictions. The JV may also fund research or studies to investigate Apo E mimetic molecules, including AEM-28 and analogs, for treatment of acute coronary syndrome.

## Manufacturing

Currently, third parties certified under Good Manufacturing Practices manufacture AZX100 and AEM-28 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. AZX100 formulation and manufacturing work is focused on an injectable formulation. AEM-28 formulation and manufacturing work is focused on an infusion formulation.

## Patents, Licenses and Proprietary Rights

On January 20, 2012, we announced our intent to cease all activities related to the development of Chrysalin and to return the patent and other intellectual property we owned related to Chrysalin to the original licensor, the University of Texas Medical Branch at Galveston, Texas. Effective March 1, 2012, the intellectual property has been returned and we no longer have any interest or rights to Chrysalin.

As part of the February 27, 2006 AzERx transaction, we acquired a license from AzTE, an affiliate of Arizona State University, for worldwide rights to AZX100 for all indications. Under the license agreement with AzTE, we are required to pay patent filing, maintenance and other related patent fees as well as royalties of 3% of covered product sales and 5% of covered license revenue. These obligations will end on the expiration of the last patent. The license

is supported by patents that expire from 2019 to 2033. The license agreement is subject to termination by AzTE for events such as non-compliance with material terms of the license agreement, bankruptcy or liquidation, Force Majeure and non-payment of amounts due.

7

---

As part of the February 27, 2006 AzERx transaction we also acquired a non-exclusive license from Washington University for transduction domain carrier patents which form part of AZX100. Under the license, we are required to pay license maintenance payments and royalties of 2% of covered product sales. The license is supported by patents that expire in 2018. These obligations will end on the expiration of the last patent.

The JV we entered into on August 3, 2012, LipimetiX Development, LLC, has an Exclusive License Agreement (the "Agreement") with the University of Alabama 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). 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 2033. The Agreement also calls for annual maintenance payments of \$25,000, various milestone payments of \$50,000 to \$1,000,000 and minimum royalty payment of \$1,000,000 to \$5,000,000 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 15% of Non Royalty Income received after August 25, 2014 and a greater percentage if received before that date.

We are a development stage research and development company with no products currently approved by the FDA for marketing. We do not expect to have products approved for marketing before 2018, if ever. Accordingly, the foregoing royalty obligations currently do not affect our reported results.

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, 2013, 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](http://www.capstonethx.com). Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as well as any amendments to those reports, are available free of charge through our website as soon as reasonably practical after we file or furnish them to the U.S. Securities and Exchange Commission. Once at our website, go to the “Investors” section to locate these filings.

In March 2004, 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

#### Risks

We may from time to time make written or oral forward-looking statements, including statements contained in our filings with the Securities and Exchange Commission and our reports to stockholders. The safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 protects companies from liability for their forward looking statements if they comply with the requirements of that Act. This Annual Report on Form 10-K contains forward-looking statements made pursuant to that safe harbor. These forward-looking statements relate to future events or to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by the use of words such as “may,” “could,” “expect,” “intend,” “plan,” “seek,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “continue” or other comparable terminology. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond our control and which could materially affect actual results, levels of activity, performance or achievements. Factors that may cause actual results to differ materially from current expectations, which we describe in more detail in this section titled “Risks,” include, but are not limited to:

- the impact of our plan to preserve cash during ongoing partnering efforts, including the reduction from eighteen employees to two employees and additional steps taken towards a virtual operating model;
- unfavorable results of our product candidate development efforts, including through our LipimetiX joint venture;
- unfavorable results of pre-clinical and clinical testing, including through our LipimetiX joint venture;
- delays in obtaining, or failure to obtain FDA or comparable foreign agencies’ approvals;

- increased regulation by the FDA and other agencies;
- the introduction of competitive products;
- impairment of license, patent or other proprietary rights;
- the impact of present and future joint venture, collaborative, partnering or development agreements or the lack thereof;
- failure to successfully implement our drug development strategy for AEM-28 or AZX100;
- 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 our product candidates or secure development agreements with pharmaceutical manufacturers; and
- 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.

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.

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.

#### Risks Related to Our Business

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 AZX100 and 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 either AZX100 or 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 AZX100 and AEM-28 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. In 2011, we suspended clinical development activities for AZX100. We have not been successful in securing partnering or licensing agreements for AZX100 and there is no assurance that we will be successful in the future. Our product candidates have reached the following stages of development:

AZX100:

- |                              |  |
|------------------------------|--|
| · Scarring                   | IND filed in 2007, Phases 1a and 1b safety studies completed in 2008. Phase 2 studies on keloid scar revision and dermal scarring following shoulder surgery commenced in the first quarter of 2009. Phase 2 studies in keloid scar revision were completed and results reported in 2010 and our Phase 2 study in dermal scarring following shoulder surgery was completed and results reported in 2011. |
| · Pulmonary Fibrosis         | Pre-clinical studies   |
| · Peridural Fibrosis (Spine) | Pre-clinical studies   |

AEM-28:

- |  |                      |
|--|----------------------|
| · Homozygous Familial Hypercholesterolemia | Pre-clinical studies |
| · Severe Refractory Hypercholesterolemia   | 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 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 impact the development of our product candidates, or partnering opportunities for our product candidates.

If we cannot protect the AZX100 or 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 AZX100 and 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.

AZX100 and 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 industry, 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 in our business 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:

- 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 that conduct our clinical trials. On October 31, 2011, we reduced our staff to four employees and as of December 31, 2013, we 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 materially affect the joint venture's ability or cost to complete its current development plan for AEM-28

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, including former key employees, for the manufacture of AZX100 and AEM-28 and 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 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 LipimetiX Development, LLC 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.

On August 3, 2012, we entered into a joint venture with LipimetiX, LLC to develop the Apo E mimetic molecule AEM-28 and analogs and we contributed \$6 million to the joint venture. Our cash contribution to the joint venture represents a substantial proportion of our available cash.

The initial funded development plan will be focused on the development of treatments for Homozygous Familial Hypercholesterolemia and Refractory Hypercholesterolemia and will extend through Phase 1a and 1b/2a clinical trials. If our planned pre-clinical studies or clinical trials do not yield favorable results, the joint venture development efforts will not be successful and we may not recover our investment. Even if our development efforts are successful, a liquidity event, if any, may be insufficient in size to recover our investment.

If our joint venture, LipimetiX Development, LLC, is unable to complete the initial funded development of AEM-28 within the available budget, the joint venture could require additional funding support and the ability of the joint venture to secure a partnering/development agreement or a liquidity event may be impaired.

The budget for the development of AEM-28 by our joint venture, LipimetiX Development, LLC is limited. If the joint venture cannot complete the planned development of AEM-28 on time and within the budget, whether because of unexpected delays, or other factors, additional funding may be required. 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.



## Risks of our Industry

We are in a highly regulated field with high investment costs and high risks.

The FDA and comparable agencies in many foreign countries impose substantial limitations on the introduction of new pharmaceuticals through costly and time-consuming laboratory and clinical testing and other procedures. The process of obtaining FDA and other required regulatory approvals is lengthy, expensive and uncertain. AZX100 and AEM-28 are new drugs and subject to the most stringent level of regulatory review.

Even after we have invested substantial funds in the development of our products and even if the results of our future clinical trials are favorable, there can be no guarantee that the FDA or comparable foreign agencies will grant approval for the indicated uses or that they will do so in a timely manner.

If we successfully bring one or more products to market, there is no assurance that we will be able to successfully manufacture or market the products or that potential customers will buy them if, for example, a competitive product has greater efficacy or is deemed more cost effective. In addition, the market in which we will sell any such products is dominated by a number of large corporations that have vastly greater resources than we have, which may impact our ability to successfully market our products or maintain any technological advantage we might develop. We also would be subject to changes in regulations governing the manufacture and marketing of our products, which could increase our costs, reduce any competitive advantage we may have and/or adversely affect our marketing effectiveness.

The pharmaceutical industry is subject to stringent regulation, and failure to obtain regulatory approval will prevent commercialization of our products.

Our research, development, pre-clinical and clinical trial activities and the manufacture and marketing of any products that we 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.

In order to obtain FDA approval to commercialize any product candidate, an NDA must be submitted to the FDA demonstrating, among other things, that the product candidate is safe and effective for use in humans for each target indication. Our regulatory submissions may be delayed, or we may cancel plans to make submissions for product candidates for a number of reasons, including:

- negative or ambiguous pre-clinical or clinical trial results;
- changes in regulations or the adoption of new regulations;
- unexpected technological developments; and
- developments by our competitors that are more effective than our product candidates.

Consequently, we cannot assure that we will make our submissions to the FDA in the timeframe that we have planned, or at all, or that our submissions will be approved by the FDA. Even if regulatory clearance is obtained, post-market evaluation of our 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.

Clinical trials are subject to oversight by institutional review boards and the FDA to ensure compliance with the FDA's good clinical practice regulations, as well as other requirements for good clinical practices. We depend, in part, on third-party laboratories and medical institutions to conduct pre-clinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good

laboratory and good clinical practices. If any such standards are not complied with in our clinical trials, the FDA may suspend or terminate such trial, which would severely delay and possibly end the development of a product candidate.

We also currently and in the future will depend upon third party manufacturers of our products, which are and will be required to comply with the applicable FDA Good Manufacturing Practice regulations. We cannot be certain that our present or future manufacturers and suppliers will comply with these regulations. The failure to comply with these regulations may result in restrictions in the sale of, or withdrawal of the products from the market. Compliance by third parties with these standards and practices are outside of our direct control.

In addition, we are subject to regulation under state and federal laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other local, state, federal and foreign regulation. We cannot predict the impact of such regulations on us, although they could impose significant restrictions on our business and require us to incur additional expenses to comply.

If our competitors develop and market products that are more effective than ours, or obtain marketing approval before we do, our commercial opportunities will be reduced or eliminated.

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 AZX100 and AEM-28 and its analogs. Many 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 such competitors may achieve product commercialization before we do. If any of our competitors develops a product that is more effective than one we are developing or plan 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 products of ours, which would have a material adverse effect on our business.

For a summary of the competitive conditions relating to indications which we are currently considering for AZX100 and AEM-28 and its analogs, see Part I, Item 1 in this Report titled "Competition".

Our product candidates may not gain market acceptance among physicians, patients and the medical community, including insurance companies and other third party payors. If our product candidates fail to achieve market acceptance, our ability to generate revenue will be limited.

Even if we obtain regulatory approval for our products, market acceptance will depend on our ability to demonstrate to physicians and patients the benefits of our products in terms of safety, efficacy, and convenience, ease of administration and cost effectiveness. In addition, we believe market acceptance depends on the effectiveness of our marketing strategy, the pricing of our products and the reimbursement policies of government and third-party payors. Physicians may not prescribe our products, and patients may determine, for any reason, that our product is not useful to them. Insurance companies and other third party payors may determine not to reimburse for the cost of the product. If any of our product candidates fails to achieve market acceptance, our ability to generate revenue will be limited.

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 Relating to our Common Stock

Our stock price is volatile and fluctuates due to a variety of factors.

Our stock, which is traded in the over-the-counter market, is thinly traded and the trading price has varied significantly in the past (from a high of \$9.32 to a low of \$0.12 during the period of January 1, 2004 through December 31, 2013) and may vary in the future due to a number of factors, including:

- announcement of the results of, or delays in, preclinical and clinical studies;
- fluctuations in our operating results;
- developments in litigation to which we or a competitor is subject;
- announcements and timing of potential partnering, development collaboration or licensing transactions, merger, acquisitions, divestitures, capital raising activities or issuance of preferred stock;
- announcements of technological innovations or new products by us or our competitors;
- FDA and other regulatory actions;
- developments with respect to our or our competitors' patents or proprietary rights;
- public concern as to the safety of products developed by us or others; and
- changes in stock market analyst recommendations regarding us, other drug development companies or the pharmaceutical industry generally.

In addition, the stock market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the market price of our stock. Furthermore, because our common stock is traded on the OTCQB and has limited trading volume, an investment in our stock is not liquid.

Additional authorized shares of our common stock available for issuance may have dilutive and other material effects on our stockholders.

We are authorized to issue 100,000,000 shares of common stock. As of December 31, 2013, 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, 2013, we had stock options outstanding to purchase approximately 3,225,806 shares of our common stock, the exercise price of which ranges between \$0.16 per share to \$7.83 per share, warrants outstanding to purchase 46,706 shares of our common stock with an exercise price of \$6.39, warrants outstanding to purchase 117,423 shares of our common stock with an exercise price of \$1.91, 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, 2013, 48,519 shares remain available to grant under the 2005 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 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 of directors 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 of directors with three-year staggered terms;
- advance notice procedures for stockholder proposals to be considered at stockholders' meetings;
  - the ability of our board of directors to fill vacancies on the board;
  - a prohibition against stockholders taking action by written consent;
- super majority 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 of directors 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 of directors, they could enable our board of directors 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 of directors under Section 203.

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

We are permitted by our certificate of incorporation to issue up to 2,000,000 shares of preferred stock. We can issue shares of our preferred stock in one or more series and can set the terms of the preferred stock without seeking any further approval from our common stockholders or other security holders. Any preferred stock that we issue may rank ahead of our common stock in terms of dividend priority or liquidation rights and may have greater voting rights than our common stock.

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

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

Item 1B.

Unresolved Staff Comments

None.

Item 2. Properties

During the years 1998 – 2007, we leased 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. It is the same facility we leased prior to our November 2003 divestiture of our bone growth stimulation device business. Following the divestiture, we occupied approximately 20% of the building capacity and subleased some portions of the building to other companies. In July 2007, we entered into a new five-year lease for 17,000 square feet of space in the same 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. We believe the facility is well-maintained and adequate for use through the end of our lease term.

Item 3. Legal Proceedings

In April 2009, we became aware of a qui tam complaint that was 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 other companies that allegedly manufactured bone growth stimulation devices, including Orthofix International N.V., Orthofix, Inc., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. By order entered on March 24, 2009, the court unsealed the amended complaint. The amended complaint alleges various causes of action under the federal False Claims Act and state and city false claims acts premised on the contention that the defendants improperly promoted the sale, as opposed to the rental, of bone growth stimulation devices. The amended complaint also includes claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-kickback Act by providing free products to physicians, waiving patients' insurance co-payments, and providing inducements to independent sales agents to generate business. The Relator is seeking civil penalties under various state and federal laws, as well as treble damages, which, in the aggregate could exceed the financial resources of the Company.

The United States Government declined to intervene or participate in the case. On September 4, 2009, Jeffrey J. Bierman, the Relator/Plaintiff, served the amended complaint to the Company. We sold our bone growth stimulation business in November 2003 and have had no further activity in the bone growth stimulation business since that date. We intend, in conjunction with the other defendants, to defend this matter vigorously and believe that at all times our billing practices in our bone growth stimulation business complied with applicable laws. On December 4, 2009, we, in conjunction with the other defendants, moved to dismiss the amended complaint with prejudice. In response to that motion, Relator/Plaintiff filed a second amended complaint. On August 17, 2010, the Company, in conjunction with the other defendants, moved to dismiss the second amended complaint with prejudice. That motion was denied by the court on December 8, 2010. We, in conjunction with the other defendants, on January 28, 2011, filed answers to the second amended complaint. No trial date has been set. Discovery in the case is now open.

Because of the many questions of law and fact that may arise, the outcome of the litigation or its impact on our business, liquidity or financial condition is uncertain. If we are unable to successfully defend or otherwise dispose of this litigation, and the Relator/Plaintiff is awarded the damages sought, we would not be able to continue our business as it is presently conducted.

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.

	2013		2012	
	High	Low	High	Low
First Quarter	\$0.26	\$0.17	\$0.28	\$0.19
Second Quarter	\$0.24	\$0.17	\$0.21	\$0.15
Third Quarter	\$0.42	\$0.17	\$0.21	\$0.12
Fourth Quarter	\$0.38	\$0.21	\$0.20	\$0.12

As of February 28, 2014, 40,885,411 shares of our common stock were outstanding and held by approximately 779 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

## SELECTED FINANCIAL DATA

The selected financial data for the Company's development stage period, August 5, 2004 through December 31, 2013, is derived from our audited financial statements. The selected financial data should be read in conjunction with the financial statements, related notes to the financial statements and other financial information appearing elsewhere in this annual report on Form 10-K and particularly the discussion in "Management's Discussion and Analysis of Financial Condition and Results of Operations." We sold our bone growth stimulation device business ("Bone Device Business") on November 26, 2003. On August 5, 2004, we purchased substantially all the assets and the intellectual property of Chrysalis Biotechnology, Inc. ("CBI"). We became a development stage company commensurate with the CBI

acquisition. On February 27, 2006, we purchased certain assets and assumed certain liabilities of AzERx Inc. (“AzERx”). On August 3, 2012, we invested \$6,000,000 for a 60% interest in a joint venture, LipimetiX Development, LLC, to develop APO-E mimetic peptide molecule AEM-28 and its analogs. The results of the joint venture are included in our consolidated operations subsequent to the date of formation, which was August 3, 2012. The financial data as presented in the following schedule reflects the gain on the sale of the bone growth stimulation device business as discontinued operations and reflects the purchased net assets of CBI and AzERx from the dates of those respective acquisitions.

Research and Development expenses in 2005 and 2006 include expenditures related to Phase 3 and Phase 2b Chrysalin clinical trials in distal radial fracture.

On March 15, 2006, we reported results of our Phase 3 fracture repair human clinical trial. For the primary endpoint, time to removal of immobilization, no statistically significant difference was observed between placebo and a single injection of Chrysalin.

On August 29, 2006, we reported the results of interim analysis of data from our Phase 2b dose-ranging clinical trial of Chrysalin in unstable, displaced distal radius (wrist) fractures and termination of the Phase 2b study. In the dataset of 240 subjects as a group that were evaluable in the Phase 2b interim analysis, treatment with Chrysalin did not demonstrate benefit compared to placebo in the primary efficacy endpoint of time to removal of immobilization.

In 2006, we implemented a strategic shift in our development approach to our Chrysalin-based product candidates, to pursue development partnering or licensing opportunities for our Chrysalin-based product candidates, a change from our previous development history of independently conducting human clinical trials necessary to advance our Chrysalin-based product candidates to market.

Research and Development expenses in 2007 include regulatory required expenses related to the completion of the Phase 3 and Phase 2b distal radial fracture studies and expenses to file an IND in dermal scarring for AZX100. Research and Development expenses in 2008 include expenditures to complete Phase 1a and Phase 1b safety clinical trials in dermal scarring for AZX100. Research and Development expenses in 2010 and 2009 include expenditures on Phase 2 clinical trials for AZX100 in keloid scar revision and dermal scarring following shoulder surgery, which commenced in the first quarter of 2009. During 2010 we completed and reported results for our clinical trials in keloid scarring and in 2011 we completed and reported results for our Phase 2 clinical trial in dermal scarring following shoulder surgery.

On October 13, 2011, we adopted a plan to conserve cash during our ongoing partnering efforts and effected a reduction from 18 to two employees. In 2012 we took additional steps to preserve cash and move towards a virtual operating model.

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, to develop APO E mimetic peptide molecule AEM-28 and its analogs. The joint venture commenced pre-clinical studies and incurred \$2,652,000 and \$1,133,000 of expenses in 2013 and 2012, respectively, which are included in our consolidated operating results.

STATEMENTS OF OPERATIONS DATA  
(A Development Stage Company)  
(in thousands, except per share amounts)

	Years Ended December 31,					August 5, 2004 to December 31, 2008
	2013 (1)	2012	2011(1)	2010(1)	2009(2)	(3) (4) (5)
<b>Operating expenses</b>						
General and administrative	\$1,169	\$1,764	\$3,506	\$3,240	\$2,901	\$ 20,075
Research and development	3,124	2,385	6,394	8,168	11,968	73,519
Purchased in-process research and development	-	-	-	-	-	34,311
Other	-	-	-	-	-	(375 )
Total operating expenses	4,293	4,149	9,900	11,408	14,869	127,530
Interest and other income, net	(158 )	(96 )	(31 )	(356 )	(737 )	(12,634 )
Loss from continuing operations before taxes	4,135	4,053	9,869	11,052	14,132	114,896
Income taxes expense (benefit)	(21 )	-	(158 )	(181 )	(1,009 )	(7 )
Loss from continuing operations	4,114	4,053	9,711	10,871	13,123	114,889
<b>Discontinued operations</b>						
Net gain on the sale of the bone device business net of taxes \$0, \$0, \$0, \$0, \$0, (\$363) respectively	-	-	-	-	-	(2,202 )
<b>NET LOSS</b>	4,114	4,053	9,711	10,871	13,123	112,687
Less: Net loss attributable to the noncontrolling interests	(193 )	(473 )	-	-	-	-
Net loss attributable to Capstone stockholders	\$3,921	\$3,580	\$9,711	\$10,871	\$13,123	\$ 112,687
<b>Per Share Information:</b>						
Net loss basic and diluted	\$0.10	\$0.09	\$0.24	\$0.27	\$0.32	
Basic and diluted shares outstanding	40,885	40,879	40,775	40,775	40,775	

- The 2013, 2011 and 2010 income tax benefits result from Arizona state income tax legislation passed in 2010 that provides for the refund of seventy five percent of the 2012, 2011 and 2010 Arizona state research and development tax credits for entities that would otherwise not be able to utilize their 2012, 2011 and 2010 Arizona research and development tax credits to reduce 2012, 2011 and 2010 Arizona state income taxes currently payable.
- The income tax benefit in 2009 of \$1,009,000 results from the carryback of our net operating loss for federal income tax purposes for the year ended December 31, 2008 to the year ended December 31, 2003, as allowed by federal tax legislation passed in 2009.
- Research and development expenses in 2006 include recognition of a \$2,100,000 Chrysalin patent cost impairment loss. Operating expenses in 2006 included \$8,471,000 of purchased in-process research and development costs associated with the AzERx acquisition in February 2006. Income tax expenses in 2006 included the recording of a \$1,106,000 valuation allowance for a deferred tax asset related to an Alternative Minimum Tax credit carryover.
- On August 5, 2004, we completed the acquisition of CBI. Capstone expensed in-process research and development and acquisition costs of \$25.8 million.
- A net gain of \$2,048,000 was recognized on the sale of the Bone Device Business primarily due to a decrease in the risk related to the potential exposure of the representations and warranties provided in the governing asset purchase agreement.





BALANCE SHEET DATA  
(in thousands)

	December 31,				
	2013	2012	2011	2010	2009
Working capital	\$6,391	\$10,294	\$14,417	\$23,214	\$34,395
Total assets	\$7,317	\$11,591	\$14,696	\$25,288	\$37,135
Potentially redeemable equity	\$-	\$-	\$-	\$15,556	\$-
Capstone Stockholders' equity	\$7,217	\$11,104	\$14,577	\$7,916	\$34,728

Working capital and total assets at December 31, 2013, include \$2.0 million and \$2.9 million, respectively, held in and reserved for use by LipimetiX Development, LLC, and unavailable for general use by the Company.

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

OVERVIEW OF BUSINESS

Company History

Prior to November 26, 2003, we developed, manufactured and marketed proprietary, technologically advanced orthopedic products designed to promote the healing of musculoskeletal bone and tissue, with particular emphasis on fracture healing and spine repair. Our product lines included bone growth stimulation and fracture fixation devices including the OL1000 product line, SpinaLogic® and OrthoFrame/Mayo, which we sometimes refer to as our "Bone Device Business."

On November 26, 2003, we sold our Bone Device Business. Our principal business remains focused on tissue repair, although through biopharmaceutical approaches rather than through the use of medical devices.

On August 5, 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. We became a development stage entity commensurate with the acquisition. Subsequently, all of our collective efforts were focused on research and development of our Chrysalin Product Platform, with the goal of commercializing our products. (In March 2012, we returned all rights to the Chrysalin intellectual property and no longer have any interest in, or rights to, Chrysalin.)

On February 27, 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, a 24-amino acid synthetic peptide. We have an exclusive worldwide license to AZX100.

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, (see Note 10 to the financial statements included in this Annual Report) to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

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 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 refer to LipimetiX Development, LLC.



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

Our development activities for AZX100 and AEM-28 represent a single operating segment as they share the same product development path and utilize the same Company resources. As a result, we have determined that it is appropriate to reflect our operations as one reportable segment. From August 5, 2004 through December 31, 2013, we have incurred approximately \$154 million in net losses as a development stage company.

#### Description of the business

Capstone Therapeutics Corp. 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). We no longer have any interest in or rights to Chrysalin. 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.

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. Certain manufacturing and regulatory activities related to AZX100 that are required either from a statutory perspective or for reporting purposes, will continue. We are also performing limited pre-clinical studies with AZX100 in fibrosis. We are currently seeking development partnering or licensing opportunities for AZX100 in dermal scarring, pulmonary fibrosis and peridural fibrosis.

The JV has a development plan to pursue regulatory approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012). The initial development plan will extend through Phase 1a and 1b/2a clinical trials and is expected to be completed in the fourth quarter of 2014. The clinical trials will have a safety primary endpoint and an efficacy endpoint targeting reduction of LDL and non-HDL cholesterol.

Regulatory filings have been made by the JV in both Canada and Australia seeking allowance to commence the proposed clinical trials. The proposed clinical trials for AEM-28 are randomized, double-blinded, placebo-controlled studies to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending doses (Phase 1a in healthy patients) and multiple ascending doses (Phase 1b/2a in patients with Refractory Hypercholesterolemia). It is expected that the Phase 1a clinical trial will consist of 36 patients and the Phase 1b/2a will consist of 15 patients. The JV anticipates receiving allowance from regulatory authorities in Australia permitting the JV to proceed with the planned clinical trials. Based on this anticipated allowance, the JV has elected to pursue clinical trials in Australia. The JV will continue to work with Canadian regulatory authorities, and may, conditions permitting, conduct future clinical trials in Canada, the USA and other regulatory jurisdictions. The JV may also fund research or studies to investigate Apo E mimetic molecules, including AEM-28 and analogs, for treatment of acute coronary syndrome. For a description of the JV, please refer to Note 10 to our financial statements included in this Form 10-K.

The Company intends to limit its internal operations in a virtual operating model while continuing our development partnering efforts for AZX100, investigating pre-clinical, clinical or other strategic options for AZX100, 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 Prior and Current Peptide Drug Candidates.

### Apo E Mimetic Peptide Molecule – AEM-28

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 that contains 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, as an Apo E mimetic, has 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. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia, HoFH), or have Severe Refractory Hypercholesterolemia, AEM-28 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. The JV has performed pre-clinical studies with AEM-28.

### AZX100

AZX100 is a novel synthetic 24-amino acid peptide and is believed to have smooth muscle relaxation and anti-fibrotic properties. AZX100 has been evaluated for medically and commercially significant applications, such as prevention of hypertrophic and keloid scarring and treatment of pulmonary and peridural fibrosis. We filed an IND for a dermal scarring indication in 2007 and completed Phase 1a and Phase 1b safety clinical trials in dermal scarring in 2008. We commenced Phase 2 clinical trials in dermal scarring following shoulder surgery and keloid scar revision in the first quarter of 2009. During 2010 we completed and reported results for our clinical trials in keloid scar revision and substantially completed our Phase 2 clinical trial in dermal scarring following shoulder surgery. We completed and reported our Phase 2 clinical trial in dermal scarring following shoulder surgery in 2011. We have an exclusive worldwide license to AZX100. In the first quarter of 2012 we ceased clinical development of AZX100, our principal drug candidate, in dermal scarring. We are currently performing limited pre-clinical studies in fibrosis. We are currently focused on development partnering or licensing opportunities for AZX100 in dermal scarring, pulmonary fibrosis and peridural fibrosis.

---

## 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 \$56 million at December 31, 2013.

25

---

Patents: Patent license rights were recorded at \$1,045,000, their estimated fair value on the date they were acquired, August 3, 2012. Their cost will be amortized on a straight-line basis over the key patent life of eighty months. At December 31, 2013, accumulated amortization totaled \$222,000. 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.

Legal and Other Contingencies: As discussed in Part I, Item 3 of this Form 10-K under the heading “Legal Proceedings” and in Note 11, “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. However, the outcome of legal proceedings and claims brought against the Company are subject to significant uncertainty. Therefore, if the qui tam legal matter is resolved against the Company in excess of management’s expectations, the Company’s financial statements could be materially adversely affected.

As discussed in Note 10, “Joint Venture for Development of Apo E Mimetic Peptide Molecule AEM-28 and Analogs” in Notes to Financial Statements included in this 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.

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, 2013 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 10 to our Financial Statements included in this Annual Report, "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.

Results of Operations Comparing Year Ended December 31, 2013 and 2012.

**General and Administrative (“G&A”) Expenses:** G&A expenses related to our ongoing operations were \$1,169,000 in 2013 compared to \$1,764,000 in 2012. Administration expenses declined primarily due to a decrease in our lease expenses caused by a reduction in office space occupied, effective March 1, 2013, and the reduction from four employees to two employees in the second quarter of 2012.

**Research and Development Expenses:** Research and development expenses were \$3,124,000 for 2013 compared to \$2,385,000 for 2012. Our research and development expenses increased in 2013 compared to 2012 primarily due to the operating expenses of LipimetiX Development, LLC, which totaled (net of intercompany transactions) \$2,652,000 for 2013, and \$1,133,000 for 2012, partially offset by a decline of AZX100 research activity.

**Interest and Other Income, Net:** Interest and Other Income, Net, increased from \$96,000 in 2012 to \$158,000 in 2013 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, while 2012 included a gain of \$80,000 from the sale of lab equipment.

**Net Loss attributable to Capstone Therapeutics stockholders:** We incurred a net loss in 2013 of \$3.9 million compared to a net loss of \$3.6 million in 2012. The net loss from 2013 benefited from a reduction in internal operations, but this beneficial effect was offset by inclusion of the operating expenses of LipimetiX Development, LLC. Net loss includes operating expenses of LipimetiX Development, LLC, which totaled (net of intercompany transactions) \$2,652,000 for 2013, and \$1,133,000 for 2012, net of net loss allocated to noncontrolling interests of \$193,000 for 2013 and \$473,000 for 2012.

Results of Operations Comparing Year ended December 31, 2012 and 2011

**General and Administrative (“G&A”) Expenses:** G&A expenses related to our ongoing operations were \$1,764,000 in 2012 compared to \$3,506,000 in 2011. The decline in administrative expenses between periods resulted from the reduction in staff in the fourth quarter of 2011 and other actions taken by the Company to wind down internal operations and move to a virtual operating model.

**Research and Development Expenses:** Research and development expenses were \$2,385,000 for 2012 compared to \$6,394,000 for 2011. Our research and development expenses decreased in the year ended December 31, 2012 compared to 2011, primarily due to the reduction in staff in the fourth quarter of 2011 and other actions taken by the Company to wind down internal operations and move to a virtual operating model. This decrease was partially offset by the operating expenses of LipimetiX Development, LLC, of \$1,133,000 (net of intercompany transactions) for 2012.

**Interest and Other Income, Net:** Interest and other income, net increased from \$31,000 in 2011 to \$96,000 in 2012 due to the recognition of a \$80,000 gain on the sale of lab equipment in the second quarter of 2012.

**Net Loss attributable to Capstone Therapeutics stockholders:** We incurred a net loss attributable to Capstone Therapeutics stockholders, in 2012 of \$3.6 million compared to a net loss of \$9.7 million in 2011. The decrease in the net loss for the year ended December 31, 2012 compared to 2011 resulted primarily from the reduction in staff in the fourth quarter of 2011 and other actions taken by the Company to wind down internal operations and move to a virtual operating model. This decrease was partially offset by costs of approximately \$139,000 related to the joint venture transaction and the operating expenses of LipimetiX Development, LLC, of \$1,133,000 (net of intercompany transactions) net of the net loss of \$473,000 allocated to noncontrolling interest for 2012.





## Liquidity and Capital Resources

We have historically financed our operations through operating cash flows and public and private sales of equity securities. However, with the sale of our Bone Device Business in November 2003, we sold all of our revenue producing operations. Since that time, we have relied on our cash and investments to finance all our operations, the focus of which has been research and development of our product candidates. We received approximately \$100 million in cash from the sale of our Bone Device Business. On February 27, 2006, we entered into an agreement with Quintiles (see Note 15 to our Annual Report on Form 10-K filed with the Securities Exchange Commission on March 5, 2008), which provided an investment by Quintiles in our common stock, of which \$2,000,000 was received on February 27, 2006 and \$1,500,000 was received on July 3, 2006. In 2010, we received a tax refund of \$1,009,000 from the tax year 2003, related to federal tax legislation recorded in the fourth quarter of 2009, and in 2010 we were awarded a Therapeutic Discovery Project federal grant of \$244,000. In 2011, we received an Arizona State income tax refund for the 2010 tax year of \$181,000. We also received additional Arizona State income tax refunds of \$158,000 in 2012 for the 2011 tax year and \$21,000 in 2013 for the 2012 tax year. We received net proceeds of \$4,612,000 from the exercise of stock options during our development stage period, \$176,000 from the sale of lab equipment and furniture and \$152,000 from the conversion of an insurance company, in which we were a policy holder, from mutual to private ownership.

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 to the Joint Venture. The Joint Venture has used \$4.0 million of its cash through December 31, 2013. At December 31, 2013, we had cash and cash equivalents of \$6.3 million, of which \$2.0 million is held in, and reserved for use by, LipimetiX Development, LLC and unavailable for general use by the Company.

If we continue our plan to limit internal operations in a virtual operating model in 2014, we currently estimate that we will expend in the range of \$4.0 million in 2014, which includes approximately \$2.5 million by LipimetiX Development LLC, of which the joint venture has \$2.0 million at December 31, 2013, with the remaining \$0.5 million to be either allocated from general Company funds or obtained from other sources, and excludes litigation costs related to the qui tam action, which cannot be estimated at this time and could be significant. Currently our planned operations in 2014 consist of continuing our development partnering efforts for AZX100, investigating pre-clinical, clinical or other strategic options for AZX100, monitoring and participating in the management of LipimetiX Development LLC’s AEM-28 and its analogs development activities, and maintaining the required level of corporate governance and reporting required to comply with Securities and Exchange Commission rules and regulations.

Our future research and development and other expenses will vary significantly from prior periods and depend on the Company’s decisions on its future AZX100 development plans, results of our efforts to create shareholder value with AZX100, LipimetiX Development LLC operations and qui tam litigation activity.

We anticipate that our cash and short-term investments at December 31, 2013 will be sufficient to meet our presently projected cash and working capital requirements for the next twelve months. However, 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 substantial 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. We cannot currently predict the amount of funds that will be required to bring the qui tam action to a final resolution.



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, 2013 and December 31, 2012, consolidated statements of operations, changes in equity and cash flows for each of the years in the two-year period ended December 31, 2013, and the consolidated statements of operations, changes in equity and cash flows for the period of August 5, 2004 through December 31, 2013, together with the related notes and the report of Moss Adams LLP, our independent registered public accounting firm, 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. (a development stage company) 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, 2013

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, 2013, 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 January 17, 2012, our Board of Directors (the "Board") voted to reduce the size of our Board from six members to three members. Concurrent with this action, Robert J. Spiegel, MD, William M. Wardell, MD, Ph.D. and Augustus A. White III, MD, Ph.D. resigned from the Board.

John M. Holliman, III

John M. Holliman III, 60, 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 twenty-five years, concentrating in the medical/biotech industries. Mr. Holliman earned a BBA in Finance and a MBA from Southern Methodist University and a Master of International Management from the Thunderbird School of Global Management. During his career Mr. Holliman has gained substantial executive and board level experience in business, finance and operations. The Board believes the experience and knowledge of Mr. Holliman qualifies him to serve on our board.

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

Fredric J. Feldman, Ph.D., 73, 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 forty 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., 74, 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 Dr. Feldman.

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 Dr. Feldman are “independent directors”, as defined in Nasdaq Listing Rule 5605(a)(2).

#### EXECUTIVE OFFICERS

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

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

Name	Age	Title
John M. Holliman, III	60	Executive Chairman and Principal Executive Officer
Randolph C. Steer, MD, Ph.D.	64	Consultant
Les M. Taeger	63	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 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

In March 2004, the Company adopted a code of ethics that applies to all of its employees and has particular sections that apply only to its principal executive officer and senior financial officers. The Company has posted the text of its code of ethics on its website ([www.capstonethx.com](http://www.capstonethx.com)), under the “Investors” section under the link “Corporate Governance” “Code of Ethics”. In addition, the Company will promptly disclose on its website (1) the nature of any amendment to its code of ethics that applies to its principal executive officer and senior financial officers, and (2) the nature of any waiver, including an implicit waiver, from a provision of its code of ethics that is granted to one of these specified officers, the name of such officer who is granted the waiver and the date of the waiver.

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

## SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Under the securities laws of the United States, the Company's directors, its executive officers and any persons holding more than 10% of the Company's Common Stock are required to report their initial ownership of the Company's Common Stock and any subsequent changes in that ownership to the SEC. Specific due dates for these reports have been established, and the Company is required to disclose any failure to file by these dates. The company believes that all of these filing requirements were satisfied during the year ended December 31, 2013, except for Form 4's, filed with the SEC on October 30, 2013 by Randolph C. Steer and Leslie M. Taeger, each for options granted on October 25, 2013, to purchase 10,000 shares of the Company's common stock, that required reporting on or before October 29, 2013.

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 Awards (\$)(1)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Fredric J. Feldman, Ph.D.	49,000		4,000	-	-	-	53,000
Elwood D. Howse, Jr.	49,000		4,000	-	-	-	53,000

(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, 2013, the Company paid 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. On June 10, 2005, the Board of Directors approved an annual award to each director of a non-qualified stock option to purchase 10,000 shares of the Company's Common Stock. The Company granted to each director non-qualified options to acquire 10,000 shares at a price of \$0.17 per share on January 1, 2013 (fair value of

\$1,000). These options vested immediately and were granted at the closing market price on the date of grant. The Company also granted to each director, non-qualified stock options to acquire 27,000 shares at a price of \$0.21 on February 28, 2013 (fair value \$3,000). These options vested 50% on February 28, 2013 and 50% on February 28, 2014. All options have been granted with ten-year terms.

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

The Board of Directors also approved an award on January 1, 2013, to each director of \$25,000 in lieu of an annually-scheduled award of the Company's restricted common stock.

Director Outstanding Equity Awards at Fiscal Year-End

Name	Option Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Options Exercise Price (\$)	Option Expiration Date
(a)	(b)	(c)	(d)	(e)	(f)
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
	* 25,500	25,500		0.16	2/28/2023
Various directors:					
(1) (2) (3)	30,000			7.40	1/23/2014
(1) (2) (3)	10,000			6.25	12/31/2014
(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)	13,500	13,500		0.21	2/28/2023
Feldman, Fred (1)					
Holliman, John (2) * Vest on 2/28/2014					
Howse, Elwood (3) All other directors options were fully vested on 12/31/2013					



## EXECUTIVE COMPENSATION

### The Compensation Committee's Conclusion

The Compensation Committee, at its meeting held at the beginning of the fiscal year, formulates its recommendations regarding what areas of the 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 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 (increased to \$135,000 for 2014) 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.

### 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 2013, the Company granted options to employees to purchase 181,000 shares of the Company's Common Stock with the exercise price determined by the closing market price on the date of grant (\$0.17 to \$0.35) and an aggregate grant date fair value of \$26,000. This grant included grants to the named executives (Holliman 61,000 shares, Steer 61,000 shares and Taeger 39,000 shares).





#### Common Stock Awards

There were no common stock awards in 2013.

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

Our executive employee participates in group health, dental, life, and disability programs and participates in our 401K plan 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 analogs, a class of Cardiovascular drugs targeting indications related to lowering blood cholesterol levels, completing the formation of the joint venture LipimetiX Development LLC (JV), and who will participate in the management of 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 JV to the Company after the Company has received 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 will vest 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. There will be accelerated vesting upon the sale of the Company's interest in JV. To continue vesting, participants must be an employee or active consultant of the Company.

## SUMMARY COMPENSATION TABLE

The following table sets forth, with respect to the years ended December 31, 2013, 2012 and 2011, 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 (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
John M. Holliman, III Executive Chairman (Principal Executive Officer)	2013	100,000	-	-	7,000	-	-	41,000 (1)	148,000
	2012	100,000	-	3,000(3)	14,000	-	-	16,000(1)	133,000
	2011	179,000	-	19,000(3)	3,000	-	-	264,000(1)(2)	465,000
Randolph C. Steer, MD, Ph.D., Consultant (former President)	2013	120,000	-	-	9,000	-	-	-	129,000
	2012	120,000	25,000	-	12,000	-	-	-	157,000
	2011	276,000	-	-	19,000	-	-	325,000 (2)	620,000
Les M. Taeger Chief Financial Officer (Principal Financial Officer)	2013	120,000	-	-	6,000	-	-	-	126,000
	2012	120,000	25,000	-	8,000	-	-	-	153,000
	2011	237,000	-	-	10,000	-	-	242,000 (2)	489,000

- Mr. Holliman is a member of the Board of Directors and as a director, received compensation of \$41,000, \$16,000 and \$64,000, in cash, in 2013, 2012 and 2011, respectively, and an annual grant of an option to purchase 10,000 shares of the Company's Common Stock. Mr. Holliman received total director's compensation (Board fees, stock awards and option grants) of \$48,000, \$20,000 and \$67,000 in 2013, 2012 and 2011, respectively, as more fully described in the Compensation of Directors section of this Annual Report on Form 10-K. Fair value of the grants at the date of the grants was determined using the Black-Scholes model as described, for 2013, in Note 5 to the Financial Statements included in this Annual Report on Form 10-K, for 2012, in Note 5 to our Annual Report on form 10-K filed with the Securities and Exchange Commission on March 14, 2013 and for 2011, in Note 5 to the Annual Report on form 10-K filed with the Securities and Exchange Commission on March 21, 2012.
- On October 31, 2011, the employment of Mr. Holliman and Dr. Steer was terminated and Mr. Taeger's salary was reduced from \$242,000 per year to \$120,000. These actions triggered severance clauses in their employment agreements requiring the payment of severance of one year's base salary to each executive officer. For a description

of the employment agreements with our named executive officers, please see “Employment Contract, Termination of Employment, and Change-in-Control Arrangements” below.

3. On January 17, 2011, Mr. Holliman was awarded 50,000 shares of restricted stock which vested on January 17, 2012. On January 1, 2012, along with the other members of the Board of Directors, Mr. Holliman was awarded 10,000 shares of common stock.

#### OPTION GRANTS / STOCK AWARDS

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

Name	Grant Date	Grants of Plan-based Awards		Exercise or Base Price of Option Awards (\$/Share)	Grant Date Fair Value of Stock and Option Awards (1) (\$)
		All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)		
(a)	(b)	(i)	(j)	(k)	(l)
John M. Holliman, III Executive Chairman	1/1/13	-	10,000	0.17	1,000
	2/28/13	-	51,000	0.21	6,000
Randolph C. Steer, MD, Ph.D. Consultant	2/28/13	-	51,000	0.21	6,000
	10/25/13	-	10,000	0.35	3,000
Les M. Taeger Chief Financial Officer	2/28/13	-	29,000	0.21	3,000
	10/25/13	-	10,000	0.35	3,000

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

## OUTSTANDING EQUITY AWARDS AT FISCAL YEAR END

Name	Option Awards					
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date		
(a)	(b)	(c)	(e)	(f)		
John M. Holliman, III	30,000	-	7.40	1/23/2014		
	10,000	-	6.25	12/31/2014		
	10,000	-	4.90	1/2/2016		
	25,000	-	1.75	5/12/2016		
	200,000	-	1.75	5/12/2016		
	10,000	-	1.43	12/31/2017		
	10,000	-	1.35	12/31/2018		
	50,000	-	1.02	2/21/2018		
	25,000	-	0.70	10/30/2018		
	10,000	-	0.42	1/1/2019		
	125,000	-	0.45	2/3/2019		
	10,000	-	0.72	1/1/2020		
	100,000	-	0.82	2/4/2020		
	10,000	-	0.58	1/1/2021		
	10,000	-	0.26	1/1/2022		
	65,000	-	0.17	5/18/2022		
	65,000	-	0.16	8/9/2022		
	10,000	-	0.17	1/1/2023		
	*	25,500	25,500	0.21	2/28/2023	
	Randolph C. Steer, MD, Ph.D.	200,000	-	1.75	5/12/2016	
50,000		-	1.53	5/21/2017		
50,000		-	1.02	2/21/2018		
75,000		-	0.45	2/3/2019		
50,000		-	0.82	2/4/2020		
50,000		-	0.67	1/17/2021		
65,000		-	0.17	5/18/2022		
65,000		-	0.16	8/9/2022		
*		25,500	25,500	0.21	2/28/2023	
**		5,000	5,000	0.35	10/25/2023	
Les M. Taeger	150,000	-	5.15	1/16/2016		
	150,000	-	1.70	6/2/2016		
	14,706	-	1.02	2/21/2018		
	50,000	-	0.45	2/3/2019		
	35,000	-	0.82	2/4/2020		
	25,000	-	0.67	1/17/2021		
	45,000	-	0.17	5/18/2022		
	45,000	-	0.16	8/9/2022		
	*	14,500	14,500	0.21	2/28/2023	
	**	5,000	5,000	0.35	10/25/2023	

\*

Vest on 2/28/2014

\*\*

Vest on 10/25/2014

40

---

EMPLOYMENT CONTRACTS, TERMINATION OF EMPLOYMENT, AND  
CHANGE-IN-CONTROL ARRANGEMENTS

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

Effective October 31, 2011, the employment of Mr. Holliman was terminated which resulted in the acceleration of the vesting of the options to purchase shares of the Company's common stock held by Mr. Holliman, so that his options became exercisable, and payment of his severance benefit. Subsequent to October 31, 2011, Mr. Holliman has continued his role as Executive Chairman under a consulting agreement, which provides for compensation at an annual rate of \$100,000. Mr. Holliman did not receive a bonus in 2013.

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

Effective October 31, 2011, the employment of Dr. Steer was terminated which resulted in the acceleration of the vesting of the options to purchase shares of the Company's common stock held by Dr. Steer, so that his options became exercisable, and payment of his severance benefits. Subsequent to October 31, 2011, Dr. Steer has continued to provide services under a consulting agreement, which provides for compensation at an annual rate of \$120,000. Dr. Steer did not receive a bonus in 2013. Dr. Steer's compensation rate for 2014 will be \$135,000.

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

Effective October 31, 2011, Mr. Taeger's annual base salary was reduced to \$120,000 and the Company's bonus plan was terminated. Mr. Taeger did not receive a bonus in 2013. Mr. Taeger's salary for 2014 will be \$135,000.

Under the Company's stock option plans, upon the occurrence of a merger in which the Company is not the surviving entity, a sale of substantially all of the assets of the Company, an acquisition by a third party of 100% of the Company's outstanding equity securities or a similar reorganization of the Company, 75% of all unvested options will vest, with the balance vesting equally over 12 months or according to the individual's vesting schedule, whichever is earlier. If the option holder loses his position with the Company as a result of the merger or sale, 100% of his options will immediately vest. Additionally, the Company's 1997 Stock Option Plan and 2005 Equity Incentive Plan provide that, upon a merger, consolidation or reorganization with another corporation in which the Company is not the surviving corporation, outstanding options shall be substituted on an equitable basis for options for appropriate shares of the surviving corporation, or optionees shall receive cash in exchange for cancellation of outstanding options.

At December 31, 2013, unvested options held by named executive officers had intrinsic value of \$41,000 and accordingly, accelerated vesting clauses if triggered at December 31, 2013, would have provided \$41,000 of additional compensation to the named executive officers.





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

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of the Company's Common Stock at February 28, 2014 with respect to (i) each person known to the Company to own beneficially more than five percent of the outstanding shares of the Company's Common Stock, (ii) each director of the Company, (iii) each of the named executive officers and (iv) all directors and executive officers of the Company as a group. At February 28, 2014 there were 40,885,411 shares of the Company's Common Stock outstanding.

Beneficial Owner	Common Stock Beneficially Owned (1)	
	Number	Percent of Class
Fredric J. Feldman (2)	492,064	1.1
John M. Holliman, III (3)	1,340,272	3.1
Elwood D. Howse, Jr. (4)	489,203	1.2
Randolph C. Steer (5)	733,298	1.7
Les M. Taeger (6)	613,280	1.4
BVF Group (7)	7,755,688	19.0
Lloyd Miller, III (8)	7,926,389	19.4
All directors and executive officers as a group (9)	3,668,117	8.2

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

(2) Includes 266,500 shares Dr. Feldman has a right to acquire upon exercise of stock options. Voting and investment power shared with spouse.

(3) Includes 828,000 shares Mr. Holliman has a right to acquire upon exercise of stock options, 3,000 shares indirectly owned as trustee and 1,658 shares indirectly owned as trustee of Valley Ventures III, LP.

(4) Includes 266,500 shares Mr. Howse has a right to acquire upon exercise of stock options.

(5) Includes 688,000 shares Dr. Steer has a right to acquire upon exercise of stock options.

(6) Includes 568,706 shares Mr. Taeger has a right to acquire upon exercise of stock options.

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

(8) Lloyd Miller, III, is not a related party or otherwise affiliated with the Company, its directors or officers, and the principal business office of the Reporting Person is located at 222 Lakeview Avenue, Suite 160-365, West Palm Beach, Florida 33401

(9) Includes 2,617,706 shares directors and executive officers have a right to acquire upon exercise of stock options.

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



## EQUITY COMPENSATION PLANS

The following provides tabular disclosure of the number of securities to be issued upon the exercise of outstanding options, the weighted average exercise price of outstanding options, and the number of securities remaining available for future issuance under equity compensation plans as of December 31, 2013, aggregated into two categories - plans that have been approved by stockholders and plans that have not. See Note 5 to the financial statements included in this Annual Report on Form 10-K for additional information on our equity compensation plans.

Plan Category:	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(c)	(b)	(c)
Equity Compensation Plans approved by Security Holders	3,225,806	\$1.52	48,519
Equity Compensation Plans not approved by Security Holders	N/A	N/A	N/A
Total	3,225,806	\$1.52	48,519

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

The Board of Directors was composed of five outside directors, who were independent directors under Nasdaq Listing Rule 5605(a)(2). On April 5, 2006, Mr. Holliman became Executive Chairman and Principal Executive Officer of the Company and is no longer an independent director under Nasdaq Listing Rule 5605(a)(2). On January 17, 2012, Drs. Spiegel, Wardell and White resigned from the Board of Directors. Currently, the Board of Directors is composed of two outside directors who are independent directors and one director who is not an independent director, under Nasdaq Listing Rule 5605(a)(2).

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The Board of Directors reviews transactions with related parties, but has no formal policies in place with respect to such reviews or the approval of such transactions. During 2013 there were no reported related party transactions with directors, executive officers or other related parties, which might have required disclosure under SEC rules or which were otherwise material to the Company.

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

## Item 14. Principal Accountant Fees and Services

The following table sets forth the aggregate fees billed to the Company for the years ended December 31, 2013 and December 31, 2012 by our principal accounting firm Moss Adams LLP.

Type of Fee	Amount	
	2013	2012

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

Audit Fees (1)	\$ 111,000	\$ 132,000
Audit-Related Fees (2)	-	7,000
Total Audit and Audit-Related Fees	111,000	139,000
Tax Fees (3)	-	-
All Other Fees (4)	-	-
Total Fees	\$ 111,000	\$ 139,000

43

---

- (1) Audit fees include fees for services rendered in connection with the audits of the Company's financial statements for the fiscal years ended December 31, 2013 and 2012 and reviews of the financial statements included in the Company's quarterly reports on Form 10-Q during the applicable fiscal year.
- (2) Audit-related fees would include fees for services rendered for matters such as a business combination, sales of shares of the Company's common stock, and responses to accounting and reporting-related matters.
- (3) Tax fees would include fees for services rendered for tax compliance, preparation of original and amended tax returns, claims for refunds and other tax services.
- (4) Our principal accounting firms did not perform nor bill the Company for any other services during the fiscal years ended December 31, 2013 and 2012 that are appropriately classified as "All Other Fees."

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

Consistent with the rules of the Securities and Exchange Commission regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation for, and overseeing the work of, the independent auditor. In recognition of this responsibility, the Audit Committee has included in its charter the responsibility to pre-approve "all auditing services and permitted non-auditing services proposed to be performed by the independent auditor, subject to the de minimis exceptions for non-audit services that were not recognized as non-audit services at the time of engagement and which are subsequently approved by the committee prior to completion of the audit." No fees were paid to the independent auditor pursuant to the "de minimis" exception to the foregoing pre-approval policy in 2013.

#### PART IV

##### Item 15. Exhibits and Financial Statement Schedules

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

1. Financial Statements.

The following financial statements of Capstone Therapeutics Corp. and Report of our Independent Registered Public Accounting Firm are presented in the "F" pages of this report:

Report of Independent Registered Public Accounting Firm.

Consolidated Balance Sheets - December 31, 2013 and 2012.

Consolidated Statements of Operations - Each of the years in the two-year period ended December 31, 2013 and for the period of August 5, 2004 through December 31, 2013.

Consolidated Statements of Changes in Equity - Each of the years in the two-year period ended December 31, 2013 and for the period of August 5, 2004 through December 31, 2013.

Consolidated Statements of Cash Flows - Each of the years in the two-year period ended December 31, 2013 and for the period of August 5, 2004 through December 31, 2013.

Notes to Consolidated Financial Statements.

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



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

(b) Exhibits

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

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

45

---

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CAPSTONE THERAPEUTICS CORP.

Date: March 27, 2014

By /s/ John M. Holliman, III  
John M. Holliman, III  
Executive Chairman

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

Signature	Title	Date
/s/ John M. Holliman, III John M. Holliman, III	Executive Chairman (Principal Executive Officer) and Director	March 27, 2014
/s/ Fredric J. Feldman Fredric J. Feldman, Ph.D.	Director	March 27, 2014
/s/ Elwood D. Howse, Jr. Elwood D. Howse, Jr.	Director	March 27, 2014
/s/ Les M. Taeger Les M. Taeger	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 27, 2014

S-1

---



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

Capstone Therapeutics Corp. (“the Company”)  
(Formerly OrthoLogic Corp.)  
Exhibit Index to Annual Report on Form 10-K  
For the Year Ended December 31, 2013

Exhibit No.	Description	Incorporated by Reference To:	Filed Or Furnished Herewith
3.1	Amended and Restated Certificate of Designation of Series A Preferred Stock, executed June 19, 2007	Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission (“SEC”) on June 25, 2007 (“June 25th 2007 8-K”)	
3.2	Bylaws of the Company	Exhibit 3.4 to the Company’s Amendment No. 2 to Registration Statement on Form S-1 (No. 33-47569) filed with the SEC on January 25, 1993 (“January 1993 S-1”)	
3.3	Certificate of Incorporation, as amended through May 21, 2010	Exhibit 3.1 to the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2010, filed with the SEC on August 9, 2010	
4.1	Class A Warrant Agreement dated February 24, 2006, between OrthoLogic Corp. and PharmaBio Development Inc. (d/b/a NovaQuest)	Exhibit 4.1 to the Company’s Current Report on Form 8-K filed with the SEC on March 3, 2006	
4.2	Class A Warrant Agreement dated June 30, 2006 by and between OrthoLogic Corp. and PharmaBio Development Inc	Exhibit 4.1 to the Company’s Current Report on Form 8-K filed with the SEC on July 6, 2006	
4.3	Amended and Restated Class B Warrant Agreement dated February 24, 2006, and amended and restated as of June 30, 2006, between OrthoLogic Corp. and PharmaBio Development Inc. (d/b/a NovaQuest) (asterisks located within exhibit denote information that has been redacted pursuant to a request for confidential treatment filed with the SEC)	Exhibit 4.4 to the Company’s Amendment No. 1 to Registration Statement on Form 8-A/A, filed with the SEC on May 25, 2010.	
10.1	Form of Indemnification Agreement(*)	Exhibit 10.16 to the Company’s January 1993 S-1	
10.2	1997 Stock Option Plan of the Company, as amended and approved by the stockholders (1)	Exhibit 4.3 to the Company’s Registration Statement on Form S-8, filed with the SEC on March 2, 2005	
10.3	Form of Incentive Stock Option Grant Letter for use in connection with the Company’s 1997 Stock Option Plan (**)	Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on January 4, 2005	
10.4	Form of Non-qualified Stock Option Grant Letter for use in connection	Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on January 19, 2006	

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

- with the Company's 1997 Stock Option Plan (\*\*)
- 10.5 Director Compensation Plan, effective June 10, 2005 (1) Exhibit 10.2 to the Company's Quarterly Report Form 10-Q for the quarterly period ended June 30, 2005, filed with the SEC on August 9, 2005
- 10.6 Employment Agreement dated January 10, 2006 between the Company and Les M. Taeger (1) Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 11, 2006 (the "January 11th 8-K")
- 10.7 Intellectual Property, Confidentiality and Non-Competition Agreement between the Company and Les M. Taeger dated January 10, 2006 (1) Exhibit 10.2 to the January 11th 8-K
- 10.8 Common Stock and Warrant Purchase Agreement by and between OrthoLogic Corp. and PharmaBio Development Inc., dated February 24, 2006. Exhibit 10.1 to the Company's Registration Statement on Form S-3 filed with the SEC on April 13, 2006 (April 2006 S-3)

E-1

---

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

10.9	Registration Rights Agreement by and between OrthoLogic Corp. and PharmaBio Development Inc., dated February 24, 2006	Exhibit 4.8 to the Company's Amendment No. 1 to Registration Statement on Form 8-A/A, filed with the SEC on May 25, 2010.
10.10	Registration Rights Agreement by and between OrthoLogic Corp., AzERx, Inc., and Certain Shareholders, dated February 27, 2006	Exhibit 10.3 to the Company's April 2006 S-3
10.11	Amended and Restated License Agreement dated February 23, 2006 by and between OrthoLogic Corp. and Arizona Science Technology Enterprises, LLC	Exhibit 10.5 to the Company's Registration Statement on Form S-3 filed with the SEC on April 25, 2006
10.12	2005 Equity Incentive Plan (2005 Plan) (1)	Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 18, 2006
10.13	Form of Incentive Stock Option Grant Letters for Grants under the 2005 Plan (**)	Exhibit 10.1 to the Company's Report on Form 10-Q for the quarterly period ended June 30, 2006, filed on August 8, 2006 ("June 2006 10-Q")
10.14	Form of Non-Qualified Stock Options Grant Letter for Grants under the 2005 Plan (**)	Exhibit 10.2 to the Company's June 2006 10-Q
10.15	Form of Restricted Stock Grant Letters for Grants under the 2005 Plan (**)	Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on May 18, 2006
10.16	Amendment to Employment Agreement dated January 10, 2006 between OrthoLogic Corp. and Les Taeger (1)	Exhibit 10.3 to the Company's June 2006 10-Q
10.17	Contribution Agreement by and among LipimetiX, LLC, Capstone Therapeutics Corp., LipimetiX Development, LLC, The UAB Research Foundation, Dennis I. Goldberg, Ph.D. ("Goldberg"), Philip M. Friden, Ph.D., Eric Morrell, Ph.D., G. M. Anantharamaiah, Ph.D. and Palgunachari Mayakonda, Ph.D., Frederick Meyer, Ph.D., Michael Webb, and Jeffrey Elton, Ph.D., effective as of August 3, 2012.	Exhibit 10.1 to the Company's Quarterly Report on form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012
10.18	Limited Liability Company Agreement of LipimetiX Development, LLC, by and among LipimetiX Development, LLC, Capstone Therapeutics Corp., and the other members and managers party thereto, effective as of August 3,	Exhibit 10.2 to the Company's Quarterly Report on form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012

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

- 2012.
- |       |   |   |
|-------|---|---|
| 10.19 | First Amendment and Consent to Assignment of Exclusive License Agreement by and among The UAB Research Foundation, LipimetiX, LLC and LipimetiX Development, LLC, dated as of August 3, 2012.       | Exhibit 10.3 to the Company's Quarterly Report on form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012 |
| 10.20 | Management Agreement by and among LipimetiX Development, LLC, Benu BioPharma, Inc., Dennis I. Goldberg, Ph.D., Phillip M. Friden, Ph.D., and Eric M. Morrel, Ph.D., effective as of August 3, 2012. | Exhibit 10.4 to the Company's Quarterly Report on form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012 |
| 10.21 | Accounting Services Agreement by and among LipimetiX Development, LLC and Capstone Therapeutics Corp., effective as of August 3, 2012.  | Exhibit 10.5 to the Company's Quarterly Report on form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012 |
| 10.22 | Escrow Agreement by and among Capstone Therapeutics Corp., LipimetiX Development, LLC dated as of August 3, 2012  | Exhibit 10.6 to the Company's Quarterly Report on form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012 |

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

10.23	Exclusive License Agreement between the UAB Research Foundation and LipimetiX LLC dated August 26, 2011	Exhibit 10.7 to the Company's Quarterly Report on form 10-Q for the period ended June 30, 2012, filed with the SEC on August 10, 2012	
10.24	Capstone Therapeutics Corp. Joint Venture Bonus Plan	Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2012, filed with the SEC on November 8, 2012	
10.25	Accounting Services Agreement Amendment #1, dated August 23, 2013	Exhibit 10.1 to the Company's Quarterly Report on form 10-Q for the period ended September 30, 2013, filed with the SEC on November 12, 2013	
23.1	Consent of independent registered public accounting firm.		X
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a -14(a) of the Securities Exchange Act of 1934, as amended		X
31.2	Certification of Principal Financial and Accounting Officer Pursuant to Rule 13a - 14(a) of the Securities Exchange Act of 1934, as amended		X
32.1	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350***		X
101	The following financial information from our Annual Report on Form 10-K for the fiscal year 2013, filed with the SEC on March 27, 2014 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as December 31, 2013 and 2012, (ii) the Consolidated Statements of Operations for the years ended 2013 and 2012 and one hundred and thirteen months ended December 31, 2013, (iii) the Consolidated Statements of Cash Flows for the two years ended December 31, 2013 and 2012 and the one hundred and thirteen months ended December 31, 2012, and (iv) Notes to Consolidated Financial Statements. ***		X

(1) Management contract or compensatory plan or arrangement.

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

\*\*Capstone Therapeutics from time to time issues stock options to its employees, officers and directors pursuant to its 1997 and 2005 Stock Option Plan, as amended. The incentive stock option grant letters and non-qualified stock option grant letters that evidence these issuances differ only in such terms as the identity of the recipient, the grant date, the number of securities covered by the award, the price(s) at which the recipient may acquire the securities and the vesting schedule. Pursuant to the instructions accompanying Item 601 of Regulation S-K, Capstone has filed the form of such incentive stock option grant letter and non-qualified stock option grant letter.

\*\*\*

Furnished herewith.

FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Capstone Therapeutics Corp.

We have audited the accompanying consolidated balance sheets of Capstone Therapeutics Corp. (formerly OrthoLogic Corp.) (a development stage company) (the "Company") as of December 31, 2013 and 2012 and the related consolidated statements of operations, changes in equity, and cash flows for each of the two years in the period ended December 31, 2013 and for the period August 5, 2004 (inception) through December 31, 2013. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Capstone Therapeutics Corp. (a development stage company) as of December 31, 2013 and 2012 and the results of its consolidated operations and its cash flows for each of the two years in the period ended December 31, 2013 and for the period from August 5, 2004 (inception) through December 31, 2013, in conformity with accounting principles generally accepted in the United States.

Scottsdale, Arizona  
March 27, 2014

/s/ Moss Adams LLP

## CAPSTONE THERAPEUTICS CORP.

(A Development Stage Company)  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share and per share data)

	December 31, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents, \$2,042 reserved at December 31, 2013	\$ 6,258	\$ 10,205
Other current assets	233	383
<b>Total current assets</b>	<b>6,491</b>	<b>10,588</b>
Patent license rights, net	823	980
Furniture and equipment, net	3	23
<b>Total assets</b>	<b>\$ 7,317</b>	<b>\$ 11,591</b>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities		
Accounts payable	\$ 88	\$ 233
Other accrued liabilities	12	61
<b>Total current liabilities</b>	<b>100</b>	<b>294</b>
Equity		
Capstone Therapeutics Corp. Stockholders' Equity		
Common Stock \$.0005 par value; 100,000,000 shares authorized; 40,885,411 shares in 2013 and 2012	20	20
Additional paid-in capital	189,215	189,181
Accumulated deficit (\$154,256 at December 31, 2013 and \$150,335 at December 31, 2012, accumulated during development stage period)	(182,018 )	(178,097 )
<b>Total Capstone Therapeutics Corp. stockholders' equity</b>	<b>7,217</b>	<b>11,104</b>
Noncontrolling interest	-	193
<b>Total equity</b>	<b>7,217</b>	<b>11,297</b>
<b>Total liabilities and equity</b>	<b>\$ 7,317</b>	<b>\$ 11,591</b>

See notes to consolidated financial statements



CAPSTONE THERAPEUTICS CORP.  
(A Development Stage Company)  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(in thousands, except per share data)

	Years ended December 31,		As a Development Stage Company August 5, 2004 - December 31, 2013
	2013	2012	
<b>OPERATING EXPENSES</b>			
General and administrative	\$ 1,169	\$ 1,764	\$ 32,655
Research and development	3,124	2,385	105,558
Purchased in-process research and development	-	-	34,311
Other	-	-	(375 )
Total operating expenses	4,293	4,149	172,149
Interest and other income, net	(158 )	(96 )	(14,011 )
Loss from continuing operations before taxes	4,135	4,053	158,138
Income tax benefit	(21 )	-	(1,376 )
Loss from continuing operations	4,114	4,053	156,762
Discontinued operations - net gain on sale of the bone device business, net of taxes of \$267	-	-	(2,202 )
Net Loss	4,114	4,053	154,560
Less: Net Loss attributable to the noncontrolling interest	(193 )	(473 )	(667 )
Net Loss attributable to Capstone Therapeutics Corp. stockholders	\$ 3,921	\$ 3,580	\$ 153,893
<b>Per Share Information:</b>			
Net loss, basic and diluted, attributable to Capstone Therapeutics Corp. stockholders	\$ 0.10	\$ 0.09	
Basic and diluted shares outstanding	40,885	40,879	

See notes to consolidated financial statements

F-3

CAPSTONE THERAPEUTICS CORP.  
(A Development Stage Company)  
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY  
(in thousands)

	Capstone Therapeutics Corp. Stockholders' Equity						
	Potentially	Common			Additional Accumulated		Non
	Redeemable	Stock	Amount	Capital	Deficit	Interest	Controlling
	Equity	Shares	Paid in	Paid in	Paid in	Paid in	Total
Balance August 5, 2004 (prior to the acquisition of CBI)	\$-	34,550	\$17	\$146,125	\$(27,762 )	\$-	\$118,338
Acquisition of CBI, August 5, 2004	-	3,248	2	23,451	-	-	23,453
Acquisition of AzERx, February 27, 2006	-	1,355	1	7,763	-	-	7,764
Exercise of common stock options	-	997	-	4,579	-	-	4,579
Stock-based compensation cost	-	-	-	3,505	-	-	3,505
Compensation earned on stock awards	-	494	-	1,200	-	-	1,200
Sale of common stock	-	1,263	1	3,375	-	-	3,376
Common stock purchased and retired	-	(1,132 )	( 1 )	(1,040 )	-	-	(1,041)
Recognized uncertain tax position	-	-	-	-	(363 )	-	(363)
Reclassification of share-based awards liability	-	-	-	116	-	-	116
Recognition of potentially redeemable equity, net of amortization	15,556	-	-	-	(15,556 )	-	(15,556)
De-recognition of potentially redeemable equity, net of amortization	(15,556)	-	-	-	15,556	-	15,556
Net loss August 5, 2004 through December 31, 2011	-	-	-	-	(146,392)	-	(146,392)
Balance December 31, 2011	-	40,775	20	189,074	(174,517)	-	14,577
Formation of Joint Venture	-	-	-	-	-	666	666
Stock-based compensation cost	-	110	-	107	-	-	107
Net loss	-	-	-	-	(3,580 )	(473)	(4,053)
Balance December 31, 2012	-	40,885	20	189,181	(178,097)	193	11,299
Stock-based compensation cost	-	-	-	34	-	-	34
Net loss	-	-	-	-	(3,921 )	(193)	(4,114)
Balance December 31, 2013	\$-	40,885	\$20	\$189,215	\$(182,018)	\$-	\$7,217

See notes to consolidated financial statements

## CAPSTONE THERAPEUTICS CORP.

(A Development Stage Company)

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		As a Development Stage Company August 5, 2004 - December 31, 2013
	2013	2012	2013
<b>OPERATING ACTIVITIES</b>			
Net loss	\$ (4,114 )	\$ (4,053 )	\$ (154,560 )
Non cash items:			
Deferred tax expense	-	-	770
Depreciation and amortization	173	29	4,144
Non-cash stock-based compensation	34	107	4,965
Gain on sale of bone device business	-	-	(2,298 )
In-process research and development	-	-	34,311
Change in other operating items:			
Interest, income taxes and other current assets	150	375	1,475
Accounts payable	(145 )	156	(883 )
Accrued liabilities	(49 )	19	(3,004 )
Cash flows used in operating activities	(3,951 )	(3,367 )	(115,080 )
<b>INVESTING ACTIVITIES</b>			
Expenditures for furniture and equipment, net	-	-	(1,044 )
Proceeds from sale of assets	4	172	7,176
Cash paid for assets of AzERx/CBI	-	-	(4,058 )
Cash paid for patent rights	-	(378 )	(1,028 )
Purchases of investments	-	-	(282,538 )
Maturities of investments	-	-	340,476
Cash flows provided by (used in) investing activities	4	(206 )	58,984
<b>FINANCING ACTIVITIES</b>			
Net proceeds from stock option exercises	-	-	4,612
Net proceeds from sale of stock	-	-	3,376
Common stock purchases	-	-	(1,041 )
Cash flows provided by financing activities	-	-	6,947
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(3,947 )</b>	<b>(3,573 )</b>	<b>(49,149 )</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>10,205</b>	<b>13,778</b>	<b>55,407</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 6,258</b>	<b>\$ 10,205</b>	<b>\$ 6,258</b>
<b>Supplemental Disclosure of Non-Cash Investing Activities -</b>			
<b>LipimetiX/AzERx/CBI Acquisitions:</b>			
Current assets acquired		\$ -	\$ 29
Patent rights acquired		1,045	3,187
Liabilities acquired, and accrued acquisition costs		-	(457 )
Original investment reversal		-	(750 )

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

In-process research and development acquired	-	34,311
Noncontrolling interest	(667 )	(667 )
Common stock issued for acquisition	-	(31,217 )
Cash paid	\$ 378	\$ 4,436

See notes to consolidated financial statements

F-5

---

CAPSTONE THERAPEUTICS CORP.  
(A Development Stage Company)  
NOTES TO FINANCIAL STATEMENTS

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Overview of the Business

Capstone Therapeutics Corp. 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). We no longer have any interest in or rights to Chrysalin. 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.

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. Certain manufacturing and regulatory activities related to AZX100 that are required either from a statutory perspective or for reporting purposes, will continue. We are also performing limited pre-clinical studies with AZX100 in fibrosis. We are currently seeking development partnering or licensing opportunities for AZX100 in dermal scarring, pulmonary fibrosis and peridural fibrosis.

The JV has a development plan to pursue regulatory approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012). The initial development plan will extend through Phase 1a and 1b/2a clinical trials and is expected to be completed in the fourth quarter of 2014. The clinical trials will have a safety primary endpoint and an efficacy endpoint targeting reduction of LDL and non-HDL cholesterol.

Regulatory filings have been made by the JV in both Canada and Australia seeking allowance to commence the proposed clinical trials. The proposed clinical trials for AEM-28 are randomized, double-blinded, placebo-controlled studies to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending doses (Phase 1a in healthy patients) and multiple ascending doses (Phase 1b/2a in patients with Refractory Hypercholesterolemia). It is expected that the Phase 1a clinical trial will consist of 36 patients and the Phase 1b/2a will consist of 15 patients. The JV anticipates receiving allowance from regulatory authorities in Australia permitting the JV to proceed with the planned clinical trials. Based on this anticipated allowance, the JV has elected to pursue clinical trials in Australia. The JV will continue to work with Canadian regulatory authorities, and may, conditions permitting, conduct future clinical trials in Canada, the USA and other regulatory jurisdictions. The JV may also fund research or studies to investigate Apo E mimetic molecules, including AEM-28 and analogs, for treatment of acute coronary syndrome. For a description of the JV, please refer to Note 10 to our financial statements included in this Form 10-K.

The Company intends to limit its internal operations in a virtual operating model while continuing our development partnering efforts for AZX100, investigating pre-clinical, clinical or other strategic options for AZX100, 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 Prior and Current Peptide Drug Candidates.

### Apo E Mimetic Peptide Molecule – AEM-28

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 that contains 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, as an Apo E mimetic, has 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. For patients that lack LDL receptors (Homozygous Familial Hypercholesterolemia, HoFH), or have Severe Refractory Hypercholesterolemia, AEM-28 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. The JV has performed pre-clinical studies with AEM-28.

### AZX100

AZX100 is a novel synthetic 24-amino acid peptide and is believed to have smooth muscle relaxation and anti-fibrotic properties. AZX100 has been evaluated for medically and commercially significant applications, such as prevention of hypertrophic and keloid scarring and treatment of pulmonary and peridural fibrosis. We filed an IND for a dermal scarring indication in 2007 and completed Phase 1a and Phase 1b safety clinical trials in dermal scarring in 2008. We commenced Phase 2 clinical trials in dermal scarring following shoulder surgery and keloid scar revision in the first quarter of 2009. During 2010 we completed and reported results for our clinical trials in keloid scar revision and substantially completed our Phase 2 clinical trial in dermal scarring following shoulder surgery. We completed and reported our Phase 2 clinical trial in dermal scarring following shoulder surgery in 2011. We have an exclusive worldwide license to AZX100. In the first quarter of 2012 we ceased clinical development of AZX100, our principal drug candidate, in dermal scarring. Certain manufacturing and regulatory projects related to AZX100 that are either required from a statutory perspective or for reporting purposes will continue to their completion. We are also performing limited pre-clinical studies in fibrosis. We are currently focused on development partnering or licensing opportunities for AZX100 in dermal scarring, pulmonary fibrosis and peridural fibrosis.

### Company History

Prior to November 26, 2003, we developed, manufactured and marketed proprietary, technologically advanced orthopedic products designed to promote the healing of musculoskeletal bone and tissue, with particular emphasis on fracture healing and spine repair. Our product lines included bone growth stimulation and fracture fixation devices are referred to as our “Bone Device Business.”

On November 26, 2003, we sold our Bone Device Business. Our principal business remains focused on under-served medical conditions, although through biopharmaceutical approaches rather than through the use of medical devices.

On August 5, 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. We became a development stage entity commensurate with the acquisition. Subsequently, our efforts were focused on research and development of Chrysalin with the goal of commercializing our product candidates. (In March 2012, we returned all rights to the Chrysalin intellectual property and no longer have any interest in, or rights to, Chrysalin.

On February 27, 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.

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, (see Note 10 to these financial statements) to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

Our development activities represent a single operating segment as they shared the same product development path and utilized the same Company resources. As a result, we determined that it is appropriate to reflect our operations as one reportable segment. Through December 31, 2013, we have incurred \$154 million in net losses as a development stage company.

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 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 refer to LipimetiX Development, LLC.

**Basis of presentation.** The accompanying financials statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

**Use of estimates.** The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, and expenses in our financial statements and accompanying notes. Management bases its estimates on historical experience and various other assumptions believed to be reasonable. Although these estimates are based on management’s assumptions regarding current events and actions that may impact the Company in the future, actual results may differ from these estimates and assumptions.

Our Development Stage significant estimates include the Chrysalis Biotechnology, Inc. and AzERx purchase price allocations, income taxes, contingencies, accounting for stock-based compensation and accounting for the formation and consolidation of LipimetiX Development, LLC.

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

**Cash and cash equivalents.** Cash and cash equivalents consist of cash on hand and cash deposited with financial institutions, including money market accounts, and investments purchased with an original or remaining maturity of three months or less when acquired. Cash and cash equivalents include \$2.0 million held in, and reserved for use by, LipimetiX Development, LLC.

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





Research and development expenses. Research and development represents both costs incurred internally for research and development activities, as well as costs incurred to fund the research activities with which we have contracted and certain payments regarding the clinical testing of our product candidates. Research and development costs are generally expensed when incurred. Nonrefundable advance payments are capitalized and recorded as expense when the respective product or service is delivered.

Accrued Clinical. Accrued clinical represents the liability recorded on a per subject basis of the costs incurred for our human clinical trials. Total patient costs are based on the specified clinical trial protocol, recognized over the period of time service is provided to the subject. We had no active clinical trials at December 31, 2013.

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

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

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

The Company recorded stock-based compensation of \$34,000 in 2013 and \$107,000 in 2012, which increased the net loss. Loss per weighted average basic and diluted shares outstanding increased by less than \$0.01 per share in 2013 and \$0.01 per share in 2012 due to stock-based compensation.

Loss per common share. In determining loss per common share for a period, we use weighted average shares outstanding during the period for primary shares and we utilize the treasury stock method to calculate the weighted average shares outstanding during the period for diluted shares. Utilizing the treasury stock method for the year ended December 31, 2013, 765,000 shares were determined to be outstanding and excluded from the calculation of diluted loss per share because they were anti-dilutive. At December 31, 2013, options and warrants to purchase 3,389,935 shares of our common stock, at exercise prices ranging from \$0.16 to \$7.83 per share, were outstanding.

Income Taxes. Under ASC Topic 740 "Income Taxes" ("ASC 740"), income taxes are recorded based on current year amounts payable or refundable, as well as the consequences of events that give rise to deferred tax assets and liabilities. We base our estimate of current and deferred taxes on the tax laws and rates that are estimated to be in effect in the periods in which deferred tax liabilities or assets are expected to be settled or realized. Pursuant to ASC 740, we have determined that the deferred tax assets at December 31, 2013 and 2012 require a full valuation allowance given that it is not "more-likely-than-not" that the assets will be recovered.

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

Based on our evaluation upon the adoption of ASC 740 on January 1, 2007 and in accordance with ASC 740, the Company recognized a cumulative-effect adjustment of \$363,000 at January 1, 2007, increasing its liability for unrecognized tax benefits, interest, and penalties and increasing accumulated deficit. Subsequent to adoption of ASC 740, each period we evaluate the tax years that remain open for assessment for federal and state tax purposes. At December 31, 2013, tax years 2009 through 2013 remain open.

During 2008, the 2003 statute of limitations expired in various states, other than Arizona. As a result, the December 31, 2007 ASC 740 reserve of \$363,000 was no longer required as of December 31, 2008. This has been reflected as an income tax benefit in the Statements of Operations in 2008. In 2009, the remaining tax issues were settled with the State of Arizona and the remaining unrecognized tax benefit of \$638,000 was recognized.

We may, from time-to-time, be assessed interest or penalties by major tax jurisdictions, although any such assessments historically have been minimal and immaterial to our financial results. The Company recognizes accrued interest and penalties, if applicable, related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2013 and 2012, the Company did not recognize a material amount in interest and penalties.

Put rights. The put rights were considered embedded equity derivatives within our common stock under derivatives accounting standards. The fair value of the put rights has been bifurcated from the value of our potentially redeemable equity and we recognized subsequent changes in the fair value of the put rights within the statement of operations. The put rights expired on June 30, 2011.

Potentially redeemable equity. The potential obligation at December 31, 2010, created by the put rights, to purchase shares of its common stock, assuming redemption of 100% of the Company's outstanding shares of common stock at December 31, 2010, and using the estimated put price determined as defined in our Certificate of Incorporation, was reclassified at December 31, 2010 to potentially redeemable equity. This amount was adjusted each reporting period to reflect changes in the put right redemption obligation. The put rights expired on June 30, 2011, ending the potential redemption obligation.



Patents. Patent license rights were recorded at \$1,045,000, their estimated fair value on the date they were acquired, August 3, 2012. Their cost will be amortized on a straight-line basis over the key patent life of eighty months. At December 31, 2013, accumulated amortization totaled \$222,000. If a change in conditions occurs, that indicates a material change in the future utility of the patent license rights, an evaluation will be performed to determine if impairment of the asset has occurred, and if so, the impairment will be recorded.

Joint Venture Accounting. The Company entered into a joint venture in which it has contributed \$6,000,000, and the noncontrolling interests have contributed certain patent license rights. Neither the Company nor the noncontrolling interests have an obligation to contribute additional funds to the joint venture or to assume any joint venture liabilities or to provide a guarantee of either joint venture performance or any joint venture liability. The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. Joint venture losses were recorded on the basis of common ownership equity interests (60% Company / 40% noncontrolling interests) until common ownership equity was reduced to \$0. Subsequent joint venture losses are being allocated to the preferred ownership equity (100% Company). Subsequent to March 31, 2013, all joint venture losses are being allocated to the Company.

#### Legal and Other Contingencies

As discussed in Note 11 "Contingency – Legal Proceedings" the Company is subject to legal proceedings and claims that arise in the course of business. The Company records a liability when it is probable that a loss has been incurred and the amount is reasonably estimable. There is significant judgment required in both the probability determination and as to whether an exposure can be reasonably estimated. In the opinion of management, there was not at least a reasonable possibility the Company may have incurred a material loss with respect to loss contingencies. However, the outcome of legal proceedings and claims brought against the Company are subject to significant uncertainty. Therefore, if the qui tam legal matter is resolved against the Company in excess of management's expectations, the Company's financial statements could be materially adversely affected.

Legal costs related to contingencies are expensed as incurred and were not material in either 2013 or 2012.

## 2.INVESTMENTS

At December 31, 2013 and December 31, 2012, investments were classified as held-to-maturity securities, as we do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. Such classification requires these securities to be reported at amortized cost unless they are deemed to be permanently or other-than-temporarily impaired in value.

As of December 31, 2013 and 2012, all investments were in investments with maturities less than 90 days and are included in cash and cash equivalents.

## 3. FURNITURE AND EQUIPMENT

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

	December 31,	
	2013	2012
Machinery and equipment	\$221	\$601
Furniture and fixtures	34	57
Leasehold improvements	-	36
	255	694
Less accumulated depreciation and amortization	(252 )	(671 )
Total	\$3	\$23

Depreciation and leasehold improvement amortization expenses for the years ended December 31, 2013 and 2012, and for the period of August 5, 2004 through December 31, 2013 were \$11,000, \$47,000 and \$1,374,000, respectively.

## 4. INCOME TAXES

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

	December 31,	
	2013	2012
Accruals and reserves	\$1	\$1
Valuation allowance	(1 )	(1 )
Total current	-	-
NOL, AMT and general business credit carryforwards	56,050	55,039
Difference in basis of fixed assets	3	114
Accruals and reserves	274	522
Difference in basis of intangibles	13	13
Valuation allowance	(56,340 )	(55,688 )
Total non current	-	-
Total deferred income taxes	\$-	\$-

ASC 740 requires that a valuation allowance be established when it is more-likely-than-not that all or a portion of a deferred tax asset will not be realized. Changes in valuation allowances from period-to-period are included in the tax provision in the period of change. In determining whether a valuation allowance is required, we take into account all evidence with regard to the utilization of a deferred tax asset including past earnings history, expected future earnings, the character and jurisdiction of such earnings, unsettled circumstances that, if unfavorably resolved, would adversely affect utilization of a deferred tax asset, carryback and carryforward periods, and tax strategies that could potentially enhance the likelihood of realization of a deferred tax asset. Management has evaluated the available evidence about future taxable income and other possible sources of realization of deferred tax assets and has established a valuation allowance of approximately \$56 million at December 31, 2013 and 2012. The valuation allowance at both 2013 and 2012 includes approximately \$2.7 million for net operating loss carry forwards that relate to stock compensation expense for income tax reporting purposes that upon realization, would be recorded as additional paid-in capital. The valuation allowance reduces deferred tax assets to an amount that management believes will more likely than not be realized.

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

	Years Ended December 31		As a Development Stage Company August 5, 2004 - December 31, 2013
	2013	2012	2013
Provision (benefit) for income taxes			
Current	\$ (21 )	\$ -	\$ (2,482 )
Deferred	-	-	1,106
Income tax provision (benefit)	\$ (21 )	\$ -	\$ (1,376 )

The 2013 income tax benefit results from Arizona state income tax legislation passed in 2010 that provides for the refund of seventy five percent of the 2012 Arizona state research and development tax credit for entities that would otherwise not be able to utilize their 2012 Arizona research and development tax credits to reduce 2012 Arizona state income taxes currently payable.

The results of the Company's Phase 3 Chrysalin fracture repair human clinical trial, which were received in 2006, resulted in a change in our planned clinical pathway and timeline for our Chrysalin fracture repair indication. This change, when factored with our current significant net operating loss carryforwards and current period net loss, resulted in a revision of our estimate of the need for a valuation allowance for the previously recorded deferred tax asset related to an AMT credit carryover from tax year 2003. Due to the uncertainty that the deferred tax asset would be realized, we recorded a valuation allowance for the full amount of the deferred tax asset (\$1,106,000) at December 31, 2006. Federal tax legislation enacted in the fourth quarter of 2009, allowed for the carryback of net operating losses incurred in 2008 to the 2003 tax year and eliminated for 2003, the AMT limit on use of more than 90% of a net operating loss to offset currently taxable income. This change generated a refund of \$1,009,000 for the AMT tax paid for tax year 2003 and a reversal of the previously established valuation allowance for the 2003 AMT credit and was recorded in income taxes at December 31, 2009.

We have accumulated approximately \$143 million in federal and \$43 million in state net operating loss carryforwards ("NOLs") and approximately \$6 million of research and development and alternative minimum tax credit carryforwards. The federal NOLs expire between 2023 and 2033. The Arizona state NOL's expire between 2014 and 2033. The availability of these NOL's to offset future taxable income could be limited in the event of a change in ownership, as defined in Section 382 of the Internal Revenue Code.

The AzERx and CBI acquisitions were treated as tax free reorganizations under Internal Revenue Code Section 368 and therefore resulted in a carryover basis and no income tax benefit for the related acquisition costs, including in-process research and development costs.

A reconciliation of the difference between the provision (benefit) for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows for the years ended December 31, 2013 and 2012 and for the period of August 5, 2004 through December 31, 2013 (in thousands):

	Years Ended December		As a
	31		Development
	2013	2012	Stage Company
			August 5, 2004 -
			December 31,
			2013
Income tax provision (benefit) at statutory rate	\$ (1,333 )	\$ (1,217 )	\$ (53,531 )
State income taxes	(138 )	(165 )	(6,096 )
Purchased in-process research and development	-	-	12,533
Research credits	(74 )	9	(6,013 )
Change in uncertain tax position reserve	-	-	(363 )
Expiration of state NOL	548	450	4,029
Other	324	472	2,345
Change in valuation allowance	652	451	45,720
Net provision (benefit)	\$ (21 )	\$ -	\$ (1,376 )

## 5. STOCKHOLDERS' EQUITY

The number of common shares reserved for issuance under the OrthoLogic 1987 option plan was 4,160,000 shares. This plan expired during October 1997. In May 1997, our stockholders adopted a new stock option plan (the "1997 Plan"). The 1997 Plan reserved for issuance 1,040,000 shares of Common Stock. Subsequent to its original adoption, the Board of Directors and stockholders approved amendments to the 1997 Plan that increased the number of shares of common stock reserved for issuance to 4,190,000. The 1997 Plan expired in March 2007. In May 2006, our stockholders approved the 2005 Equity Incentive Plan (the "2005 Plan") and reserved 2,000,000 shares of our common stock for issuance. In May 2009, our stockholders approved the reservation of an additional 1,250,000 shares of common stock for issuance under the 2005 Plan, which increased the total shares available for grant under the 2005 Plan to 3,250,000 shares. At December 31, 2013, 48,519 shares remained available to grant under the 2005 Plan (the 1997 plan and the 2005 plan are collectively referred to as "The Plans"). Two types of options may be granted under the Plans: options intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code (the "Code") and other options not specifically authorized or qualified for favorable income tax treatment by the Code. All eligible employees may receive more than one type of option. Any director or consultant who is not an employee of the Company shall be eligible to receive only nonqualified stock options under the Plans.

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

We used the Black-Scholes model with the following assumptions to determine the total fair value of \$34,000 and \$59,000 for options to purchase 255,000 and 595,000 shares of our common stock issued during 2013 and 2012, respectively.

	2013	2012
Risk free interest rate	0.7%	0.8%
Volatility	77%	74%
Expected term from vesting	4.6 Years	4.0 Years

### Summary

Non-cash stock compensation cost for the year ended December 31, 2013, totaled \$34,000. In the Statement of Operations for the year ended December 31, 2013, non-cash stock compensation expense of \$33,000 was recorded as a general and administrative expense and \$1,000 was recorded as a research and development expense.

Non-cash stock compensation cost for the year ended December 31, 2012, totaled \$107,000. In the Statement of Operations for the year ended December 31, 2012, non-cash stock compensation expense of \$98,000 was recorded as general and administrative expense and \$9,000 was recorded as research and development expense.

No options were exercised in the years ended December 31, 2013 and 2012.

At December 31, 2013, the remaining unamortized non-cash stock compensation costs totaled approximately \$2,000, which will be recognized ratably over the period ending December 31, 2014, with an estimated weighted average period of one year.

A summary of option activity under our stock option plans for the years ended December 31, 2013 and 2012 is as follows:

	2013			2012	
	Number of Options	Weighted average exercise price	Weighted average remaining contractual term (years)	Number of Options	Weighted average exercise price
Options outstanding at the beginning of the year:	3,218,264	\$ 1.71		3,372,501	\$ 2.08
Granted	255,000	\$ 0.22		595,000	\$ 0.17
Exercised	-	\$ -		-	
Expired / Forfeited	(247,458 )	\$ 2.65		(749,237 )	\$ 2.16
Outstanding at end of year	3,225,806	\$ 1.52	4.96	3,218,264	\$ 1.71
Options exercisable at year-end	3,115,384	\$ 1.57	4.77	3,083,680	\$ 1.78
Options vested and expected to vest at year end	3,150,504	\$ 1.55	4.83	3,123,618	\$ 1.76

On January 17, 2011, the Board of Directors of the Company granted John M. Holliman 50,000 shares of restricted common stock (fair value on the date of grant of \$19,000), which vested January 17, 2012. On January 17, 2012, the Board of Directors was each granted 10,000 shares of unrestricted common stock (total fair value on the date of grant of \$18,000). The Company had no unvested common stock share awards as of December 31, 2013 and no common stock awards were made in 2013.





It is the Company's policy to issue options from stockholder approved incentive plans. However, if the options are issued as an inducement for an individual to join the Company, the Company may issue stock options outside of stockholder approved plans. The options granted to employees under stockholder approved incentive plans have a ten-year term and normally vest over a two to four-year period of service. All stock options are granted with an exercise price equal to the current market value on the date of grant and, accordingly, stock options have no intrinsic value on the date of grant. Based on the closing market price of the Company's common stock at December 31, 2013 of \$0.26, stock options exercisable or expected to vest at December 31, 2013, have intrinsic value of \$6,000.

#### Warrants

At December 31, 2013, the Company has fully vested warrants outstanding to purchase 46,706 shares of the Company's common stock with an exercise price of \$6.39 per share which expire in February 2016, and fully vested warrants outstanding to purchase 117,423 shares of the Company's common stock with an exercise price of \$1.91 per share which expire in July 2016. No warrants were exercised during the years ended December 31, 2013 or 2012.

### 6.COMMITMENTS

During 1998 through 2007, we were obligated under a non-cancelable operating lease agreement for a Tempe, Arizona office and research facility. Rent expense for the years ended December 31, 2013 and 2012, and for the period of August 5, 2004 through December 31, 2013 was \$82,000, \$263,000 and \$5,177,000, respectively. We subleased portions of the Tempe facility to other tenants and approximately 45% of the Tempe facility was subleased through December 2007, which offset our lease expense. The Company recorded \$2,299,000 of sublease income for the period of August 5, 2004 through December 31, 2007. The Company had no sublease income in the years subsequent to 2007.

On July 19, 2007, the Company entered into a lease, which became effective upon the expiration of its previous lease, for 17,000 square feet of space in the same Tempe, Arizona facility. This lease calls for monthly rental payments of \$22,000, plus a proportionate share of building operating expenses and property taxes. The term of this lease is sixty months from March 1, 2008. In January of 2013, this lease was amended to extend the lease to February 28, 2015, with the rentable square feet of space reduced to 2,845 square feet and monthly rental payments of \$4,000.

#### 7. 401(K) PLAN

We adopted a 401(k) plan for our employees on July 1, 1993 and terminated the plan on November 30, 2012. There were no 401(k) Company contributions in 2013 or 2012.

### 8.AUTHORIZED PREFERRED STOCK

We have 2,000,000 shares of authorized preferred stock, the terms of which may be fixed by our Board of Directors. We presently have no outstanding shares of preferred stock. While we have no present plans to issue any additional shares of preferred stock, our Board of Directors has the authority, without stockholder approval, to create and issue one or more series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

9. AUTHORIZATION OF COMPANY BUY-BACK OF COMMON STOCK

On March 5, 2008, we announced that our Board of Directors approved a stock repurchase program for up to five percent of our then outstanding common shares. The shares could be repurchased from time to time in open market transactions or privately negotiated transactions at our discretion, subject to market conditions and other factors. There were approximately 41.8 million shares of common stock outstanding on March 5, 2008. On May 21, 2010, our Board of Directors canceled the stock repurchase program.

We did not purchase any shares in 2010 prior to cancellation of the program, and we did not purchase any shares in 2009. During the year ended December 31, 2008, we repurchased and retired 1,131,622 shares of our common stock at a total cost of \$1,041,000.

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

On August 3, 2012, we entered into a Contribution Agreement with LipimetiX LLC to form a joint venture, LipimetiX Development LLC (“JV”), to develop Apo E mimetic molecules, including AEM-28 and analogs. The Company contributed \$6 million, which includes \$1 million for 600,000 voting common ownership units representing 60% ownership in JV, and \$5 million for 5,000,000 non-voting preferred ownership units, which have preferential distribution rights. The Contribution Agreement called for initial funding of approximately \$3.3 million and funding of the remaining approximately \$2.7 million (held in escrow) upon milestone achievement of IND allowance by the FDA or mutual agreement of both parties. By mutual agreement, on August 23, 2013, \$800,000 was released from the escrow account and additional funds will be released in 2014.

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

LipimetiX LLC was formed by the principals of Benu BioPharma, Inc. (“Benu”) and UABRF to commercialize UABRF’s intellectual property related to Apo E mimetic molecules, including AEM-28 and analogs. Benu is composed of Dennis I. Goldberg, Ph.D., Phillip M. Friden, Ph.D. and Eric M. Morrel, Ph.D. The Exclusive License 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 approximately by 2028. The Agreement also calls for annual maintenance payments of \$25,000, various milestone payments of \$50,000 to \$1,000,000 and minimum royalty payment of \$1,000,000 to \$5,000,000 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 15% of Non Royalty Income received after August 25, 2014 and a greater percentage if received before that date.

Concurrent with entering into the Contribution Agreement and the First Amendment and Consent to Assignment of Exclusive License Agreement between LipimetiX LLC, UABRF and the Company, the Company and LipimetiX LLC entered into a Limited Liability Company Agreement for JV which establishes a Joint Development Committee (“JDC”) to manage JV development activities. The JDC is composed of three members appointed by LipimetiX LLC and two members appointed by the Company. Non-development JV decisions, including the issuance of new equity, incurrence of debt, entry into strategic transactions, licenses or development agreements, sales of assets and liquidation, will be decided by a majority vote of the common ownership units.



The JV, on August 3, 2012, entered into a Management Agreement with Benu to manage JV development activities for a monthly fee of approximately \$63,000 during the twenty-seven month development period, and an Accounting Services Agreement with the Company to manage JV accounting and administrative functions with a current monthly fee of \$1,000. The Management Agreement provides for an additional performance measured incentive fee of up to \$250,000.

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

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

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

The financial position and results of operations of the joint venture are presented on a consolidated basis with the financial position and results of operations of the Company. Intercompany transactions have been eliminated. The joint venture agreement requires profits and losses to be allocated on the basis of common ownership equity interests (60% Company / 40% noncontrolling interests). However, for the Company's consolidated financial statement, joint venture losses were recorded on the basis of common ownership equity interests (60% Company / 40% noncontrolling interests) until common ownership equity was reduced to \$0. Subsequent joint venture losses are being allocated to the preferred ownership equity (100% Company). Subsequent to March 31, 2013, all joint venture losses are being allocated to the Company.

The joint venture incurred operating expenses, prior to the elimination of intercompany transactions of \$2,664,000 in 2013, of which \$2,471,000 is allocated to the Company, and \$3,847,000 for the period from August 3, 2013 (inception) to December 31, 2012, of which \$3,180,000 is allocated to the Company. The joint venture operating expenses are included in research and development expenses in the consolidated statements of operations.

Neither the Company nor the noncontrolling interests have an obligation to contribute additional funds to the joint venture or to assume any joint venture liabilities or to provide a guarantee of either joint venture performance or any joint venture liability. Losses allocated to the 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, 2013, losses totaling \$667,000 have been allocated to the noncontrolling interests.

## 11. CONTINGENCY – LEGAL PROCEEDINGS

In April 2009, we became aware of a qui tam complaint that was 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 OrthoLogic and other companies that allegedly manufactured bone growth stimulation devices, including Orthofix International N.V., Orthofix, Inc., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. By order entered on March 24, 2009, the court unsealed the amended complaint. The amended complaint alleges various causes of action under the federal False Claims Act and state and city false claims acts premised on the contention that the defendants improperly promoted the sale, as opposed to the rental, of bone growth stimulation devices. The amended complaint also includes claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-kickback Act by providing free products to physicians, waiving patients' insurance co-payments, and providing

inducements to independent sales agents to generate business. The Relator/Plaintiff is seeking civil penalties under various state and federal laws, as well as treble damages, which, in the aggregate could exceed the financial resources of the Company.

F-18

---

The United States Government declined to intervene or participate in the case. On September 4, 2009, the Relator/Plaintiff served the amended complaint on the Company. We sold our bone growth stimulation business in November 2003 and have had no further activity in the bone growth stimulation business since that date. We intend, in conjunction with the other defendants, to defend this matter vigorously and believe that at all times our billing practices in our bone growth stimulation business complied with applicable laws. On December 4, 2009, the Company, in conjunction with the other defendants, moved to dismiss the amended complaint with prejudice. In response to that motion, Relator/Plaintiff filed a second amended complaint. On August 17, 2010, the Company, in conjunction with the other defendants, moved to dismiss the second amended complaint with prejudice. That motion was denied by the court on December 8, 2010. On January 28, 2011, we, in conjunction with the other defendants, filed our answer to the second amended complaint. No trial date has been set. Discovery in the case is now open.

Based upon the currently available information, we believe that the ultimate resolution of this matter will not have a material effect on our financial position, liquidity or results of operations. However, because of many questions of law and facts that may arise, the outcome of this litigation is uncertain. If we are unable to successfully defer or otherwise dispose of this litigation, and the Relator/Plaintiff is awarded the damages sought, the litigation would have a material adverse effect on our financial position, liquidity and results of operations and we would not be able to continue our business as it is presently conducted.