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Capstone Therapeutics Corp. Form 10-K March 14, 2013

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

# FORM 10-K

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

For the fiscal year ended December 31, 2012

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)

> 1275 West Washington Street, Suite 101, Tempe, Arizona 85281 (Address of principal executive offices) Registrant's telephone number including area code: (602) 286-5520

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

Title of each className of each exchange on which registeredCommon Stock, par value \$.0005 per shareOTCQB

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required

86-0585310

(IRS Employer Identification No.)

to submit and post such files). [x] 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 Nasdaq Capital Market on June 30, 2012 was approximately \$4,500,000. 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, 2013 was 40,885,411.

## CAPSTONE THERAPEUTICS CORP. FORM 10-K ANNUAL REPORT YEAR ENDED DECEMBER 31, 2012

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## PART I

Item 1.Business

Overview of the Business

Capstone Therapeutics Corp. is a biotechnology company committed to developing a pipeline of novel therapeutic peptides aimed at helping patients with under-served medical conditions. Previously we were focused on development and commercialization of two product platforms: AZX100 and Chrysalin (TP508 or rusalatide acetate).

On October 13, 2011, the Company's Board of Directors adopted a plan to preserve cash during our ongoing partnering efforts and effected a reduction from 18 employees to four employees. At December 31, 2012, we had two employees. 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.

On January 20, 2012, we announced additional steps we took to preserve cash and move towards a virtual operating model while we continued efforts to create shareholder value through a development partnership (of clinical or pre-clinical stage assets) or other strategic transactions. Those steps included:

- We ceased clinical development of AZX100, formerly our principal drug candidate, in dermal scarring. Certain pre-clinical, manufacturing and regulatory projects related to AZX100 that are either required from a statutory perspective or have been contracted will continue to their completion.
  - We ceased all activities related to the development of TP508, our initial drug candidate, and returned the patent and other intellectual property we owned related to TP508 to the original licensor, the University of Texas Medical Branch at Galveston, Texas. We no longer have any interest in or rights to TP508.

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, (the "JV") to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

The JV intends to implement an initial development plan to file an IND and pursue FDA approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012). The initial funded development plan will extend through Phase 1a and 1b/2a clinical trials over an expected twenty-seven month period with a biomarker endpoint test targeting reduction of LDL cholesterol. 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.

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Description of Prior and Current Peptide Drug Candidates.

### 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 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 pre-clinical, manufacturing and regulatory projects related to AZX100 that are either required from a statutory perspective or have been contracted will continue to their completion. We are currently focused on development partnering or licensing opportunities for AZX100 in dermal scarring, pulmonary fibrosis and peridural fibrosis.

### Chrysalin

Chrysalin (TP508), a novel synthetic 23-amino acid peptide, is believed to produce angiogenic and other tissue repair effects in part by 1) activating or upregulating endothelial nitric oxide synthase (eNOS); 2) cytokine modulation resulting in an anti-inflammatory effect; 3) inhibiting apoptosis (programmed cell death); and 4) promoting angiogenesis and revascularization. It may have therapeutic value in diseases associated with endothelial dysfunction. We primarily investigated Chrysalin in two indications, fracture repair and diabetic foot ulcer healing. Effective January 17, 2012, we ceased all activities related to the development of Chrysalin. We returned the intellectual property related to TP508 to the University of Texas Medical Branch in March 2012 and we no longer have any interest in or rights to TP508.

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 binding domain that is removed by heparin sulfate receptors 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.

## **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.

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.

Effective January 17, 2012, we ceased all activities related to the development of Chrysalin. We returned the intellectual property related to TP508 to the University of Texas Medical Branch in March 2012 and we no longer have any interest in or rights to TP508.

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, 2012, we have incurred \$150 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" ref Capstone Therapeutics Corp. References to our Bone Device Business refer to our former business line of bone growth stimulation and fracture fixation devices, including the OL1000 product line, SpinaLogic®, OrthoFrame® and OrthoFrame/Mayo. References to our joint venture 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 is 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. In November 2011, Excaliard Pharmaceuticals announced they had entered into an agreement to be acquired by Pfizer, Inc. We have no additional information on the project development status of EXC001.

### **Pulmonary Fibrosis**

Several investigative agents are in Phase 3 clinical trials, including pirfenidone (Pirespa – Intermune), bosentan (Tracleer – Actelion Pharmaceuticals) and BIBF1120 (Boehringer, Ingelheim). Pirfenidone is approved for sale in 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.

#### Research and Development

On October 13, 2011, our Board of Directors adopted a plan to preserve cash and effected a reduction from 18 employees to four, leaving one remaining regulatory employee. At December 31, 2012, we have two administrative employees and utilize 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.

Prior to October 2011, our Pre-clinical, Clinical, Chemical Materials and Controls, Regulatory and Quality Assurance departments (research and development) consisted of approximately eighteen permanent employees who were assisted by consultants from the academic and medical practitioner fields. These individuals have extensive experience in the areas of biomaterials, animal modeling, cellular and molecular biology, clinical trial design and data management. Our Clinical department designs, initiates, monitors and manages our clinical trials. Our staff was focused on clinical trials to advance AZX100 to NDA status in a dermal indication, pre-clinical studies investigating AZX100's potential for the treatment of pulmonary fibrosis and exploring the science behind and potential of AZX100. We have been executing a development plan that included filing an IND for dermal scarring in 2007 and commencement of Phase 1 safety studies in this indication in the first quarter of 2008. Our Phase 1a study was completed in May 2008. We initiated a second safety study in dermal scarring (Phase 1b), which was completed in the fourth quarter of 2008. In the first quarter of 2009 we commenced Phase 2 clinical trials in keloid scar revision. These Phase 2 studies completed enrollment in 2009. During 2010 we completed and reported results for our Phase 2 clinical trials in keloid scarring. We also commenced in the first quarter of 2009 a Phase 2 clinical trial in dermal scarring following shoulder surgery and completed this trial in 2011. The Safety Committee reviewing all safety-related aspects of these completed Phase 1 and 2 trials was satisfied with the profile of AZX100.

We incurred expenses of \$1.3 million and \$6.4 million, in 2012 and 2011, 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 \$1.1 million relating to AEM-28 research efforts in 2012. The JV intends to implement an initial development plan to file an IND and pursue FDA approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (granted Orphan Drug designation by the FDA in 2012). The initial funded development plan will extend through Phase 1a and 1b/2a clinical trials over an expected twenty-seven month period with a biomarker endpoint test targeting reduction of LDL. 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 own 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 2022 to 2024. 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.

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 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.

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

On October 13, 2011, our Board of Directors adopted a plan to preserve cash during our ongoing partnering efforts and effected a reduction from 18 to four employees.

As of December 31, 2012, we had two fulltime 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 101, Tempe, Arizona 85281, and our telephone number is (602) 286-5520.

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

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

- the impact of our 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;
    - unfavorable results of our pre-clinical or clinical testing;
    - delays in obtaining, or failure to obtain FDA 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 collaborative, partnering or development agreements or the lack thereof;
    - failure to successfully implement our drug development strategy;
- failure to obtain additional funds required to complete clinical trials and supporting research and production efforts necessary to obtain FDA approval for our product candidates; 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. The litigation is now expected to enter the discovery phase.

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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 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 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 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. We currently intend to pursue development partnering or licensing opportunities for our product candidates. 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
· Epidural/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:

A7V100.

- the FDA 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, 2012, 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 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 FDA 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 will grant approval for the indicated uses or that it 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 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.

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

Our stock 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, 2012) 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.

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, 2012, 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, 2012, we had stock options outstanding to purchase approximately 3,218,264 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, 2012, 131,061 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;

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- 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 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, Realtor/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 Mattersand 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.

	2012		2011	
	High	Low	High	Low
First Quarter	\$0.28	\$0.19	\$0.69	\$0.40
Second Quarter	\$0.21	\$0.15	\$0.48	\$0.21
Third Quarter	\$0.21	\$0.12	\$0.40	\$0.23
Fourth Quarter	\$0.20	\$0.12	\$0.29	\$0.21

As of February 28, 2013, 40,885,411 shares of our common stock were outstanding and held by approximately 805 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.

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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, 2012, 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 \$1,133,000 of expenses in 2012, which are included in our 2012 consolidated operating results.

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

	Years Ended December 31, 2012 2011 (1) 2010 (1) 2009(2) 2008(3)					August 5, 2004 to December 31, 2007 (4) (5) (6)
Operating expenses						
General and administrative	\$1,764	\$3,506	\$3,240	\$2,901	\$2,991	\$17,084
Research and development	2,385	6,394	8,168	11,968	10,693	62,826
Purchased in-process research and development	-	-	-	-	-	34,311
Other	-	-	-	-	-	(375)
Total operating expenses	4,149	9,900	11,408	14,869	13,684	113,846
Interest and other income, net	(96)	(31)	(356)	(737)	(2,082)	(10,552)
Loss from continuing operations before taxes	4,053	9,869	11,052	14,132	11,602	103,294
Income taxes expense (benefit)	-	(158)	(181)	(1,009)	(363)	356
Loss from continuing operations	4,053	9,711	10,871	13,123	11,239	103,650
Discontinued operations						
Net gain on the sale of the bone device business net of						
taxes \$0, \$0, \$0, \$0, \$0, (\$363) respectively	-	-	-	-	-	(2,202)
NET LOSS	4,053	9,711	10,871	13,123	11,239	101,448
Less: Net loss attributable to the noncontrolling interests	(473)	-	-	-	-	-
Net loss attributable to Capstone stockholders	3,580	9,711	10,871	13,123	11,239	\$101,448
Per Share Information:						
Net loss basic and diluted	\$0.09	\$0.24	\$0.27	\$0.32	\$0.27	
Basic and diluted shares outstanding	40,879	40,775	40,775	40,775	41,078	

- 1. The 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 2011 and 2010 Arizona state research and development tax credits for entities that would otherwise not be able to utilize their 2011 and 2010 Arizona research and development tax credits to reduce 2011 and 2010 Arizona state income taxes currently payable.
- 2. 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.
- 3. The income tax benefit in 2008 resulted from a reversal of an expected income tax liability recorded on the initial adoption on January 1, 2007 of Financial Accounting Standards Board ("FASB") Interpretation No. 48 "Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109".
- 4. 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.

- 5. On August 5, 2004, we completed the acquisition of CBI. Capstone expensed in-process research and development and acquisition costs of \$25.8 million.
- 6. 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,						
	2012	2011	2010	2009	2008		
Working capital	\$10,294	\$14,417	\$23,214	\$34,395	\$44,865		
Total assets	\$11,591	\$14,696	\$25,288	\$37,135	\$49,514		
Potentially redeemable equity	\$-	<b>\$</b> -	\$15,556	\$-	\$-		
Capstone Stockholders' equity	\$11,104	\$14,577	\$7,916	\$34,728	\$47,522		

Working capital and total assets include \$4.5 million and \$5.7 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.

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" ref Capstone Therapeutics Corp. References to our Bone Device Business refer to our former business line of bone growth stimulation and fracture fixation devices, including the OL1000 product line, SpinaLogic®, OrthoFrame® and OrthoFrame/Mayo. References to our joint venture 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, 2012, we have incurred approximately \$150 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 therapeutic peptides aimed at helping patients with under-served medical conditions. Previously we were focused on development and commercialization of two product platforms: AZX100 and Chrysalin (TP508 or rusalatide acetate).

On October 13, 2011, the Company's Board of Directors adopted a plan to preserve cash during our ongoing partnering efforts and effected a reduction from 18 employees to four employees. At December 31, 2012, we had two employees. 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.

On January 20, 2012, we announced additional steps we took to preserve cash and move towards a virtual operating model while we continued efforts to create shareholder value through a development partnership (of clinical or pre-clinical stage assets) or other strategic transactions. Those steps included:

- We ceased clinical development of AZX100, formerly our principal drug candidate, in dermal scarring. Certain pre-clinical, manufacturing and regulatory projects related to AZX100 that are either required from a statutory perspective or have been contracted will continue to their completion.
- We ceased all activities related to the development of TP508, our other drug candidate, and returned the patent and other intellectual property we own related to TP508 to the original licensor, the University of Texas Medical Branch at Galveston, Texas. We no longer have any interest in or rights to TP508.

On August 3, 2012, we entered into a joint venture, LipimetiX Development, LLC, (the "JV") to develop Apo E mimetic peptide molecule AEM-28 and its analogs.

The JV intends to implement an initial development plan to file an IND and pursue FDA approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (granted Orphan Drug Designation by FDA in 2012). The initial funded development plan will extend through Phase 1a and 1b/2a clinical trials over an expected twenty-seven month period with a biomarker endpoint test targeting reduction of LDL cholesterol. 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

#### 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 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 pre-clinical, manufacturing and regulatory projects related to AZX100 that are either required from a statutory perspective or are under contract will continue to their completion. We are currently focused on development partnering or licensing opportunities for AZX100 in dermal scarring, pulmonary fibrosis and peridural fibrosis.

#### Chrysalin

Chrysalin (TP508), a novel synthetic 23-amino acid peptide, is believed to produce angiogenic and other tissue repair effects in part by 1) activating or upregulating endothelial nitric oxide synthase (eNOS); 2) cytokine modulation resulting in an anti-inflammatory effect; 3) inhibiting apoptosis (programmed cell death); and 4) promoting angiogenesis and revascularization. It may have therapeutic value in diseases associated with endothelial dysfunction. We primarily investigated Chrysalin in two indications, fracture repair and diabetic foot ulcer healing. Effective January 17, 2012, we ceased all activities related to the development of Chrysalin. We returned the intellectual property related to TP508 to the University of Texas Medical Branch in March 2012 and we no longer have any interest in or rights to TP508.

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 binding domain that is removed by heparin sulfate receptors 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.

#### 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, 2012.

Patents: Patent license rights were recorded at \$1,043,000, 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, 2012, accumulated amortization totaled \$65,000. 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 is 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 (\$10,000 monthly accounting fee paid by JV to Company) 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).

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, 2012 losses totaling \$473,000 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 is 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 are 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 (\$10,000 monthly accounting fee paid by JV to Company) have been eliminated. Joint venture losses will 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).

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.

Results of Operations Comparing Years Ended December 31, 2011 and 2010

On October 13, 2011, the Company's Board of Directors adopted a plan to preserve cash during our ongoing partnering efforts and a reduction from 18 employees to four employees. The Company has attempted to retain the services of several former key employees through consulting agreements.

General and Administrative ("G&A") Expenses: G&A expenses related to our ongoing development operations were \$3,506,000 in 2011 compared to \$3,240,000 in 2010. Our administrative expenses during 2011 reflect a comparable level of administrative activity in 2010 with the increase in expenses between periods due to severance payments resulting from the reductions in staff and officers salaries effective October 31, 2011, totaling approximately \$1.1 million, partially offset by the effect of elimination of the Company's performance based incentive bonus plan and reduced expenses from the decrease in operational activity after October 31, 2011.

Research and Development Expenses: Research and development expenses were \$6,394,000 for 2011 compared to \$8,168,000 in 2010. Our research and development expenses decreased in 2011 compared to 2010 primarily due to reduced clinical costs in 2011 compared to 2010 related to our Phase 2 clinical trials. Our Phase 2 clinical trials for keloid scar revision were completed in 2010 and our Phase 2 clinical trial in dermal scarring following shoulder surgery was substantially completed in 2010. These cost decreases were partially offset by severance costs of \$600,000 in 2011.

Interest and Other Income, Net: Interest and other income, net decreased from \$356,000 in 2010 to \$31,000 in 2011 due to the reduction in the amount available for investment and the shift in late 2010 to investments with maturities of ninety days or less. Interest and Other Income in 2010 also included a \$244,000 Therapeutic Discovery Project federal grant.

Net Loss attributable to Capstone Therapeutics stockholders: We incurred a net loss in 2011 of \$9.7 million compared to a net loss of \$10.9 million in 2010. The decrease in the net loss for 2011 compared to 2010 resulted primarily from reduced clinical costs in 2011 compared to 2010 related to our Phase 2 clinical trials, the effect of elimination of the Company's performance based incentive bonus plan and decreased operating costs after October 31, 2011. Our Phase 2 clinical trials for keloid scar revision were completed in 2010 and our Phase 2 clinical trial in dermal scarring following shoulder surgery was substantially completed in 2010. These cost decreases were partially offset by severance costs of approximately \$1.7 million in 2011.

## Liquidity and Capital Resources

We have historically financed our operations through operating cash flows and the 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 was research and development of our Chrysalin and AZX100 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, of which \$78,000 was received in 2010. In 2011, we received an Arizona State income tax refund for the 2010 tax year of \$181,000 and we received an additional Arizona State income tax refund of \$158,000 in 2012 for the 2011 tax year. We also received net proceeds of \$4,612,000 from the exercise of stock options during our development stage period and \$172,000 from the sale of lab equipment and furniture in 2012.

On August 3, 2012, we contributed \$6.0 million to the LipimetiX Development, LLC joint venture. For 2012, we used \$3.6 million of cash, of which \$1.5 million was used by LipimetiX Development, LLC. At December 31, 2012, we had cash and cash equivalents of \$10.2 million, of which \$4.5 million is held in, and reserved for use by, LipimetiX Development, LLC and unavailable for general use by the Company.

On October 13, 2011, our Board of Directors adopted a plan to preserve cash and effected a reduction from 18 employees to two employees. The Company retained the services of several former key employees through consulting agreements.

On January 20, 2012, we took additional actions to preserve cash and move towards winding down internal operations and a virtual operating model while we continued efforts to create shareholder value through a development partnership (of clinical or pre-clinical stage assets) or other strategic transactions. These additional actions included the following:

- We ceased clinical development of AZX100, formerly our principal drug candidate, in dermal scarring. Certain pre-clinical, manufacturing and regulatory projects related to AZX100 that are either required from a statutory perspective or have been contracted will continue to their completion.
- We ceased all activities related to the development of TP508, our other drug candidate, and returned the patent and other intellectual property we own related to TP508 to the original licensor, the University of Texas Medical Branch at Galveston, Texas. We no longer have any interest in or rights to TP508.

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.

The JV intends to implement an initial development plan to file an IND and pursue FDA approval of AEM-28 as treatment for Severe Refractory Hypercholesterolemia and Homozygous Familial Hypercholesterolemia (as an Orphan Drug). The initial funded development plan will extend through Phase 1a and 1b/2a clinical trials over an expected twenty-seven month period with a biomarker endpoint test targeting reduction of LDL. 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.

If we continue our plan to limit internal operations in a virtual operating model in 2013, we currently estimate that we will expend in the range of \$4.0 million in 2013, which includes approximately \$2.5 million by LipimetiX Development LLC, and excludes litigation costs related to the qui tam action, which cannot be estimated at this time and could be significant. We expect that the joint venture will expend the \$6 million (\$4.5 million remaining at December 31, 2012) over its planned twenty-seven month development period. Currently our planned operations in 2013 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, 2012 will be sufficient to meet our presently projected cash and working capital requirements for the next year. However, to complete the clinical trials and supporting research and production efforts necessary to obtain FDA 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

Balance sheets as of December 31, 2012 and December 31, 2011, statements of operations, potentially redeemable equity and stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2012, and the statements of operations, potentially redeemable equity, shareholders' equity and cash flows for the period of August 5, 2004 through December 31, 2012, 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 Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control - Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2012.

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 Annual Report on Changes in Internal Controls

There were no changes in our internal controls over financial reporting during the fiscal quarter ended December 31, 2012, 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, 59, 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 a major financial institution, and has been active in venture capital financing for over twenty 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., 72, 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., 73, 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 BSQUARE Corporation (BSQR), Formotus, Inc., BeneSol Corporation, Stella Therapeutics, Inc. and not-for-profits, Junior Achievement Worldwide and 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.

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Member of the Audit Committee
Member of the Compensation Committee
Member of the Corporate Governance/Nominating Committee

The Audit Committee, which is a separately-designated standing committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), consisted of Mr. Howse (Chairman), Dr. White and Dr. Spiegel. On January 17, 2012, Dr. White, Dr. Wardell and Dr. Spiegel resigned from our Board and from all committees. Dr. Feldman joined the Audit Committee on January 17, 2012.

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 each of the other members of the Audit Committee is an "independent director" 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	59	Executive Chairman and Principal Executive Officer
Randolph C. Steer, MD, Ph.D.	63	Consultant
Les M. Taeger	62	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. became President of the Company on April 5, 2006. Subsequent to October 31, 2011, 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 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 fellowship 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. ("CardioTech"). CardioTech is 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, specializes 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), 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, 2012, except for a Form 13G, Form 3 and Form 4, filed with the SEC on November 29, 2012 by Lloyd I. Miller, III, reflecting approximately 60 transactions that required reporting prior to November 29, 2012.

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 M Incentive Plan Compensation ( (\$)	Deferred	All Other Compensation (\$)	Total (\$)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Fredric J. Feldman, Ph.D.	22,000	3,000	9,000	-	-	-	34,000
Elwood D. Howse, Jr.	22,000	3,000	9,000	-	-	-	34,000
Robert J. Spiegel, MD (2)	4,000	3,000	1,000	-	-	-	8,000
William M. Wardell, MD, Ph.D. (2)	4,000	3,000	1,000	-	-	-	8,000
Augustus A. White, III, MD, Ph.D. (2)	4,000	3,000	1,000	-	-	-	8,000

(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.

(2) Drs. Spiegel, Wardell and White resigned from the Board on January 17, 2012.

During the year ended December 31, 2012, the Company paid directors Board Fees of \$4,000 for the first quarter and \$6,000 per quarter thereafter. All directors are eligible for a grant of nonqualified 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 \$0.26 per share on January 1, 2012 (fair value of \$1,000). These options vested immediately and were granted at the closing market price on the date of grant. All options have been granted with ten-year terms.

The Board of Directors also approved an award on January 1, 2012, to each director of 10,000 shares of the Company's common stock (fair value of \$3,000 on the date of grant).

# Director Outstanding Equity Awards at Fiscal Year-End

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Awards 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	(0)	(0)	(u)	(0)	(1)
John Wi. Hommun, 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
	* 32,500	32,50	0	0.17	5/18/2022
	65,000	,- •	•	0.16	8/9/2022
	,				
Various directors:					
(1) (2) (3)	10,000			6.13	12/31/2013
(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)	* 17,500	17,500		0.17	5/18/2022
(1) (2)	42,500			0.16	8/9/2022
Feldman, Fred (1)					
Holliman, John (2)	* Vest on 5/18/20	13			
Howse, Elwood (3)	All other directors	options were ful	lly vested on 12/31/2	2012	

## 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 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 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 2012, the Company granted options to employees to purchase 595,000 shares of the Company's Common Stock with the exercise price determined by the closing market price on the date of grant (\$0.16 to \$0.26) and an aggregate grant date fair value of \$59,000. This grant included grants to the named executives (Holliman 130,000 shares, Steer 130,000 shares and Taeger 90,000 shares).

## Common Stock Awards

On January 1, 2012, Mr. Holliman and each member of the Board of Directors, was awarded 10,000 shares of restricted stock with a fair value of \$3,000 on the date of award.

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, 2012, 2011 and 2010, 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 Compen- sation (\$)	V Nonqualified Deferred Compensation Earnings (\$)	Other nCompensatior	Total (\$)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
John M. Holliman, III	2012	100,000	-	3,000(3)	14,000(1)	-	-	16,000(1)	133,000
Executive	2011	179,000	-	19,000(3)	3,000	-	-	264,000(1)(2)	465,000
Chairman (Principal Executive Officer)	2010	<ul><li>(1)</li><li>200,000</li></ul>	-	-	50,000(1)	)-	-	64,000(1)	314,000
Randolph C. Steer, MD, Ph.D.	2012	120,000	25,000	-	12,000	-	-	-	157,000
Consultant (former	2011	276,000	-	-	19,000	-	-	325,000 (2)	620,000
President)	2010	325,000	88,000	-	23,000	-	-	-	436,000
Les M. Taeger Chief Financial	2012	120,000	25,000	-	8,000	-	-	-	153,000
Officer (Principal	2011	237,000	-	-	10,000	-	-	242,000 (2)	489,000
Financial Officer	)2010	242,000	68,000	-	16,000	-	-	-	326,000

- 1. Mr. Holliman is a member of the Board of Directors and as a director, received compensation of \$16,000, \$64,000 and \$64,000, in cash, in 2012, 2011 and 2010, 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 \$20,000, \$67,000 and \$68,000 in 2012, 2011 and 2010, 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 2012, in Note 5 to the Financial Statements included in this Annual Report on Form 10-K, for 2011, in Note 5 to our Annual Report on form 10-K filed with the Securities and Exchange Commission on March 21, 2012 and for 2010, in Note 5 to the Annual Report on form 10-K/A filed with the Securities and Exchange Commission on March 29, 2011.
- 2. 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 offers, 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.

Grants of Plan-based Awards								
Name	Grant Date	All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards (\$/Share)	Grant Date Fair Value of Stock and Option Awards (1) (\$)			
(a)	(b)	(i)	(j)	(k)	(1)			
John M. Holliman, III Executive Chairman	1/1/12	-	10,000	0.26	1,000			
	1/1/12	10,000	-	-	3,000			
	5/18/12	-	65,000	0.17	6,000			
	8/9/12	-	65,000	0.16	6,000			
Randolph C. Steer, MD, Ph.D.	5/18/12	-	65,000	0.17	6,000			
Consultant	8/9/12	-	65,000	0.16	6,000			
Les M. Taeger Chief Financial Officer	5/18/12	-	45,000	0.17	4,000			
	8/9/12	-	45,000	0.16	4,000			

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	Number of	Option	Option		
	Securities	Securities	Exercise	Expiration		
	Underlying	Underlying	Price	Date		
	Unexercised	Unexercised				
	Options (#)	Options (#)	(\$)			
	Exercisable	Unexercisable				
(a)	(b)	(c)	(e)	(f)		
John M. Holliman, III						
	10,000	)-	6.13	12/31/2013		
	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		
*	32,500	)32,500	0.17	5/18/2022		
	65,000		0.16	8/9/2022		
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			