

Capstone Therapeutics Corp.  
Form 10-K  
March 29, 2011

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

FORM 10-K

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

For the fiscal year ended December 31, 2010

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

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

Commission file number: 0-21214

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

Delaware  
(State or other jurisdiction of  
incorporation or organization)

86-0585310  
(IRS Employer Identification No.)

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

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

Title of each class	Name of each exchange on which registered
Common Stock, par value \$.0005 per share	NASDAQ Capital Market
Rights to purchase 1/100 of a share of Series A Preferred Stock	NASDAQ Capital Market

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  No

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

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "small reporting company" in Rule 12b-2 of the Exchange Act. Large accelerated filer

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

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

Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based upon the closing sale price of the registrant's common stock as reported on the Nasdaq Capital Market on June 30, 2010 was approximately \$23,400,000. 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, 2011 was 40,775,411.

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CAPSTONE THERAPEUTICS CORP.  
(Formerly OrthoLogic Corp.)  
FORM 10-K ANNUAL REPORT  
YEAR ENDED DECEMBER 31, 2010

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## PART I

### Item 1. Business

#### Overview of the Business

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.

Capstone Therapeutics Corp., referred to herein as “Capstone Therapeutics”, “Capstone”, “OrthoLogic”, “the Company”, “we”, “us”, or “our”, is a biotechnology company committed to developing a pipeline of novel therapeutic peptides aimed at helping patients with under-served medical conditions. The Company is focused on development and commercialization of two product platforms: AZX100 and Chrysalin (TP508 or rusalatide acetate).

#### AZX100

AZX100, a novel synthetic 24-amino acid peptide, is believed to relax smooth muscle which modulates blood pressure and the function of blood vessels, airways, sphincters, the gastrointestinal tract and the genitourinary tract. Sustained abnormal contraction of any of these muscles is called a spasm. Any disorders known to be associated with excessive constriction or inadequate dilation of smooth muscle represent potential applications for AZX100.

AZX100 is also believed to inhibit the fibrotic phenotype of fibroblasts and smooth muscle cells in a mechanism similar to that which causes vasorelaxation. Through phenotypic modulation of fibroblasts and smooth muscle cells, AZX100 may inhibit the scarring that results from wound healing and may mitigate fibrotic disease states in the dermis, blood vessels, lungs, liver and other organs.

AZX100 is currently being evaluated for medically and commercially significant applications, such as prevention or reduction of hypertrophic and keloid scarring and treatment of pulmonary fibrosis. Capstone has an exclusive worldwide license to AZX100. We filed an IND for a dermal scarring indication in 2007, and in 2008 we completed Phase 1a and Phase 1b safety clinical trials supporting AZX100 safety in this indication. We commenced in the first quarter of 2009 Phase 2 clinical trials in dermal scarring following arthroscopic shoulder surgery and in keloid scar revision. These Phase 2 studies completed enrollment in 2009. During 2010 we completed and reported results for our clinical studies in keloid scarring. We also substantially completed our Phase 2 clinical trial in dermal scarring following shoulder surgery. We expect to complete the analysis and report results from this study during first quarter 2011. The Company is currently exploring partnering or development collaboration opportunities for AZX100.

#### 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) modulating angiogenic factors. It may have therapeutic value in diseases associated with endothelial dysfunction.

We have conducted clinical trials for two potential Chrysalin applications: acceleration of fracture repair and diabetic foot ulcer healing. We previously conducted a pilot human study for spine fusion, and pre-clinical testing for cartilage defect repair, cardiovascular repair, dental bone repair, and tendon repair. Current efforts in support of Chrysalin are focused on identifying and exploring partnering or development collaboration opportunities. We are not currently planning additional pre-clinical or



clinical studies with Chrysalin.

### Company History

Prior to November 2003, we developed, manufactured and marketed proprietary, technologically advanced orthopedic products designed to promote the healing of musculoskeletal bone and tissue, with particular emphasis on fracture healing and spine repair. Our product lines 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.” In November 2003, we sold our Bone Device Business.

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. As a result of this acquisition, we became a development stage company. 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.

Our development activities for Chrysalin and AZX100 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, 2010, we have incurred \$137 million in net losses as a development stage company.

### Stockholder Put Right

In May 2010, our stockholders approved an amendment to our certificate of incorporation to provide each record holder of our common stock as of June 30, 2011 with the right to require us, under certain circumstances, to purchase for cash all or a portion of the shares of common stock held by such holder at a formula-based price on or about July 31, 2011. We refer to this as the put right. The exercise by stockholders of this put right could impair our ability to continue as a going concern. See "Risk Factors - Risks Related to the Put Rights" below, and Note 10 to our Financial Statements included in this Annual Report on Form 10-K for further information about the put rights.

### 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 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.

Renovo Group was conducting a Phase 3 clinical trial in Europe evaluating two different doses of recombinant TGF $\beta$ 3 (Juvista) given twice for scar revision surgery of disfiguring scars (n=350). Renovo announced on February 11, 2011, that Juvista did not meet its primary or secondary endpoints in this trial.

## Pulmonary Fibrosis

Several investigative agents are in Phase 3 clinical trials, including pirfenidone (Pirespa – Intermune), bosentan (Tracleer – Actelion Pharmaceuticals) and ambrisentan (Letairis – Gilead Sciences / GlaxoSmithKline). Pirfenidone is approved for sale in Japan and the European Union.

## Chrysalin

### Vascular Endothelial Dysfunction (VED)

Impaired nitric oxide (NO) production reduces the responsiveness of endothelial cells to angiogenic factors and causes loss of endothelial function in ischemic and inflamed blood vessels contributing to a number of chronic diseases. We hypothesize that Chrysalin may produce angiogenic and other tissue repair effects by activating or upregulating nitric oxide synthetase (NOS) in endothelial cells, and if so, that it may have potential therapeutic value in tissues and diseases exhibiting endothelial dysfunction. There are multiple VED indications with development potential. While the potential product markets are significant in size, the markets are characterized by intense competition by both large and small companies with a variety of competing technologies.

Clinical indications associated with VED include the broad areas of coronary artery disease (CAD). Insufficient blood supply to the myocardium can result in myocardial ischemia, injury, infarction, or all three. Atherosclerosis of the larger coronary arteries is the most common anatomic condition that causes diminished coronary blood flow.

Pharmacologic therapies currently in development for acute myocardial infarction include stem cell-based approaches, selective kinase inhibitors, thrombin-activatable plasminogen and other peptides.

Pharmacologic therapies commonly used in treating myocardial ischemia include 1) aspirin and anticoagulants; 2)  $\beta$  blockers; 3) nitrates; and 4) calcium channel blockers. Also, the use of angiotensin-converting enzyme (ACE) inhibitors has recently been shown to be beneficial in the treatment of myocardial ischemia. Invasive treatments such as percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass surgery (CABG) may be indicated as well.

We are in the preliminary stages of examining these disease states and the suitability of Chrysalin as a therapeutic agent to treat vascular disorders.

## Marketing and Sales

Neither Chrysalin nor AZX100 are currently available for sale and we do not expect them to be available for sale for some time into the future. Thus, we currently have no marketing or sales staff. External consultants and members of our staff provide some technical marketing support relating to the

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development of, and market need for, new potential products and additional therapeutic applications of products already under research.

#### Research and Development

Our Pre-clinical, Clinical, Chemical Materials and Controls, Regulatory and Quality Assurance departments (research and development) consist of approximately eighteen permanent employees who are assisted by consultants from the academic and medical practitioner fields. Our employees 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 has been 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 and Chrysalin. We are 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. The Safety Committee reviewing all safety-related aspects of these completed Phase 1 and 2 trials was satisfied with the profile of AZX100. We also commenced in the first quarter of 2009 a Phase 2 clinical trial in dermal scarring following shoulder surgery and substantially completed this trial in 2010.

We incurred expenses of \$8.2 million and \$12.0 million, in 2010 and 2009, respectively, related to research efforts on AZX100 and Chrysalin. Given the overlapping nature of this work, it is not possible to clearly separate research expenditures between AZX100 and Chrysalin; however, the majority of expenditures were related to AZX100 in both 2010 and 2009.

#### Manufacturing

Currently, third parties certified under Good Manufacturing Practices manufacture AZX100 and Chrysalin 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. Our current AZX100 and Chrysalin formulation and manufacturing work is focused on an injectable formulation.

#### Patents, Licenses and Proprietary Rights

As part of our purchase of CBI on August 5, 2004, the license agreements between CBI and OrthoLogic for the development, use, and marketing of the therapeutic products utilizing Chrysalin were replaced by a direct license agreement between OrthoLogic and the University of Texas. Subsequently, we entered into an agreement whereby the University of Texas assigned to us certain patents previously exclusively licensed to us. We must pay the University of Texas royalties on future sales of products, sublicense fees and various other fees in connection with filing and maintaining Chrysalin-related patents. This obligation will expire upon the expiration of the subject patents. Chrysalin has been patented in the United States and in some other countries for a number of methods of use, including cardiovascular indications. A composition of matter patent covering European countries expired in 2007 and the corresponding United States patent expires in 2011. Our other patents for Chrysalin expire between 2021 and 2024.

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 on future sales of products

that contain AZX100. These obligations will end on the expiration of the last patent. The license is supported by patents that expire from 2022 to 2024.

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 on future sales of products that contain the licensed technology. These obligations will end on the expiration of the last covered patent.

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

#### Insurance

Our business entails the risk of product liability claims. We maintain a product liability and general liability insurance policy and an umbrella excess liability policy. There can be no assurance that liability claims will not exceed the coverage limit of such policies or that such insurance will continue to be available on commercially reasonable terms or at all. Consequently, product liability claims or claims arising from our clinical trials could have a material adverse effect on our business, financial condition and results of operations. We have not experienced any material liability claims to date resulting from our clinical trials.

#### Employees

As of December 31, 2010, we had twenty-five permanent and four temporary employees in our operations, including twenty-two employees in research and development and seven in administration. 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

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

In March 2004, we adopted a code of ethics that applies to all of our employees and has particular sections that apply only to our principal executive officer and senior financial officers. We posted the text of our code of ethics on our website in the "Investors" section of our website under "Corporate Governance", "Code of Ethics." In addition, we will promptly disclose on our website (1) the nature of any amendment to our code of ethics that applies to our principal executive officer and senior financial officers, and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such officer who is granted the waiver and the date of the waiver.

## Item 1A.

## Risk Factors

## Risks

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

- 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;
  - failure to achieve market acceptance of our products;
- the impact of present and future collaborative or partnering 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;
  - failure in the future to meet the requirements for continued listing on the Nasdaq Capital Market; and
  - effect of our shareholders’ put rights on our stock price, liquidity 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 now will enter the discovery phase.

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.

#### 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 as we continue our research and development projects. 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 Chrysalin and have allocated most of our resources to bringing these product candidates to the market, either through clinical trials or partnering efforts. We may invest in other peptide or small molecule-based therapeutics in the future, but there can be no assurance that opportunities of this nature will occur at acceptable terms, conditions or timing. 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 Chrysalin 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 development 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 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 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. We have no current plans to perform additional clinical trials with Chrysalin. 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. 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 is scheduled to be completed in early 2011.
- Pulmonary Fibrosis Pre-clinical trials.

Chrysalin:

- Acceleration of Fracture Repair Phase 3 / Phase 2b human clinical trials
- Diabetic Foot Ulcer Healing Phase 1/2 human clinical trials
- Spine Fusion Phase 1/2 human clinical trials
- Cartilage Defect Repair Late stage pre-clinical trials
- Tendon Repair Early stage pre-clinical trials
- Cardiovascular Repair Pre-clinical trials
- Dental Bone Repair Pre-clinical trials

We are subject to the risk that:

- 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.

Our product candidates are all based on the same two chemical peptides, Chrysalin and AZX100. If one of our Chrysalin or AZX100 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 AZX100 or Chrysalin product candidates, or partnering opportunities for our product candidates.

If we cannot protect the Chrysalin patents, the AZX100 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 Chrysalin and AZX100 and each product resulting from Chrysalin or AZX100. 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.

Certain key Chrysalin methods of use patents have expired and other patents will expire during the development period of our Chrysalin product candidates. We believe our current patents covering formulations and specific indications are adequate to protect the value of the Chrysalin product candidates. However, if our current patents are not adequate, the value of our Chrysalin product candidates may be materially adversely impacted.

Chrysalin and AZX100 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 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. The resignation or retirement of members of senior management or scientific personnel could materially adversely affect our business prospects.

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

We rely on outside suppliers and consultants for the manufacture of Chrysalin and AZX100 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.

#### 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. Chrysalin and AZX100 are new drugs and are subject to the most stringent level of FDA review.

Even after we have invested substantial funds in the development of our Chrysalin and AZX100 products and even if the results of our future clinical trials are favorable, there can be no guarantee that the FDA will grant approval of Chrysalin and/or AZX100 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 either Chrysalin or AZX100. 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 Chrysalin and AZX100, see Part I, Item 1 in this Report titled "Competition".

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

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

Healthcare reform and restrictions on reimbursements may limit our financial returns.

Our ability to successfully commercialize our products may depend in part on the extent to which government health administration authorities, private health insurers and other third party payors will reimburse consumers for the cost of these products. Third party payors are increasingly challenging both the need for, and the price of, novel therapeutic drugs and uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third party reimbursement may not be available for our products to enable us to maintain price levels sufficient to realize an appropriate return on our investments in research and product development, which could restrict our ability to commercialize a particular product candidate.

#### Risks and Uncertainties Related to the Put Rights

In May 2010, our stockholders approved an amendment to our certificate of incorporation, to provide each record holder of our common stock as of June 30, 2011 with the right to require us, under certain circumstances, to purchase for cash all or a portion of the shares of common stock held by such holder at a formula-based price on or about July 31, 2011 (the "put right"). Unless terminated earlier, the put rights will become exercisable by holders of our common stock as of June 30, 2011. We expect to facilitate the exercise of the put rights through the use of a tender offer, informing stockholders of the



amount of cash that would be paid for each properly exercised put right and the process by which to exercise such put rights. The cash price to be paid to stockholders for each properly exercised put right will be based on a formula calculated by us as of June 30, 2011, which price is intended to approximate the per-share equivalent of 90% of our available cash (as that term is defined in our Certificate of Incorporation) as of June 30, 2011.

The uncertainty of pending litigation may cause the put rights to be unexercisable, cause the exercise of the rights to be uneconomical, affect the timing of the exercise of the put rights or affect the timing of the payments of the put price.

Our obligation to purchase shares upon exercise of the put rights is subject to various conditions. One condition is that such purchases will not violate applicable law, including Section 160 of the Delaware General Corporation Law (DGCL) relating to share repurchases that may impair capital. Because the pending qui tam litigation described in Item 3 below seeks potentially significant damages that, if awarded, could exceed our financial resources, the pendency of this claim at the time of share repurchases pursuant to the put rights could cause the share repurchases to violate Section 160 of the DGCL and the Uniform Fraudulent Transfer Act.

In addition, in determining the price per share to be paid to stockholders upon exercise of the put rights, our Board of Directors must value all contingent liabilities, including the qui tam lawsuit. Our Board of Directors may determine that, even if the probability of an unsuccessful outcome of this litigation is low, the magnitude of the potential damages that may be awarded in an unfavorable verdict is such that the value ascribed to this contingent liability for this purposes would cause the per share purchase price upon exercise of the put rights to be zero or nearly zero. Any such determination could materially and adversely impact our share price.

If holders of 100% of our Common Stock properly exercise their put rights, the put rights will terminate and our Board of Directors will propose a plan of dissolution or liquidation to our stockholders.

Our certificate of incorporation provides, among other things, that if holders of 100% of our Common Stock outstanding as of June 30, 2011 properly exercise their put rights, the put rights will immediately terminate and our Board of Directors must propose a plan of dissolution or liquidation for approval by our stockholders. We cannot be certain that our stockholders will approve any such plan or if such a plan were approved, how the liquidation or dissolution will affect the value of shares of Common Stock.

The price per share paid by us in connection with any properly exercised put rights may be substantially less or more than the price per share a stockholder may be able to obtain in the future if a stockholder elects not to exercise their put right.

Although our Board of Directors will make a good faith effort to value our assets and liabilities in connection with the exercise of any put rights, we cannot assure you that such valuations will accurately reflect the liquidation value of our non-cash assets or our outstanding and contingent liabilities. Certain of our non-cash assets, including our intellectual property portfolio, and liabilities may present significant valuation challenges. We cannot assure you that the price per share that we offer to pay pursuant to any properly exercised put right will be fair.

If our Board of Directors materially underestimates the liquidation value of our non-cash assets or materially overestimates the liquidation value of our outstanding and contingent liabilities, the price per share that we offer to pay pursuant to any properly exercised put right may be significantly less than the value of a share of our Common Stock following consummation of the put.

Alternatively, if our Board of Directors materially overestimates the liquidation value of our non-cash assets or materially underestimates the liquidation value of our outstanding and contingent liabilities,



the price per share that we offer to pay pursuant to any properly exercised put right may be significantly more than the value of a share of our Common Stock following consummation of the put.

We also cannot assure you how long or whether we will continue to operate the Company following the purchase of shares pursuant to any properly exercised put rights. However, in the event that we do continue to operate the Company after such time, it is possible that the long-term value of the shares held by our continuing stockholders will substantially exceed or be materially less than the price per share that we offer pursuant to any properly exercised put right. In part, this is because the price per share to be paid upon the exercise of a put right will be based on the liquidation value of our non-cash assets and our commitments and contingencies, as determined by our Board of Directors. The actual future value of these assets realized in an orderly liquidation or through continued operation will almost certainly be materially different than their liquidation value. Likewise, the liquidation value ascribed to contingent or uncertain liabilities will almost certainly be materially different than the actual cost to resolve such liabilities in due course.

The exercise of the put rights may trigger delisting from The Nasdaq Stock Market, if our shares are then listed on that exchange.

Under Rule 5550 of the Nasdaq Listing Rules, two of the continued listing requirements for a company that has its Common Stock listed on the Nasdaq Capital Market are that the company has:

- at least 300 beneficial and record holders other than any holder who is an executive officer, director or greater than 10% beneficial owner, and
  - at least 500,000 shares not held by any officer, director, or greater than 10% beneficial owner.

If enough holders of our Common Stock exercise the put right such that either of these continued listing requirements is no longer satisfied, our Common Stock would be delisted from the Nasdaq Capital Market. Delisting of our Common Stock could have a materially negative impact on its market value and would significantly impair its liquidity to the detriment of our continuing stockholders.

The exercise of the put rights may enable us to take the Company private.

Even if the exercise of put rights does not trigger delisting from the Nasdaq Capital Market, we may still be able, and may in fact elect, to terminate the registration of our Common Stock under Section 12 of the Exchange Act and delist our shares from the Nasdaq Capital Market. This is sometimes described as “going private.” Rule 12g-4 under the Act provides that an issuer may terminate the registration of any class of its securities registered under the Act where it has fewer than 300 holders of record of such class.

If the purchase of our Common Stock pursuant to properly exercised put rights reduces our record holder count to fewer than 300, we cannot assure you that we would not seek to take the Company private. Deregistration of our Common Stock would, among other things, terminate our periodic reporting obligations under the Act, which would mean that our continuing stockholders may have access to significantly less information about the Company following deregistration. In addition, delisting our Common Stock could have a materially negative impact on its market value and would significantly impair the liquidity of any available market for our shares, to the detriment of our continuing stockholders. At the time that stockholders must decide whether to exercise their put rights, they may not know whether we will elect to deregister our Common Stock and go private.



We may not be obligated to purchase shares pursuant to properly exercised put rights, and the put rights may terminate, which may have material adverse effect on our share price.

The put rights will terminate upon the occurrence of any one of a number of events, including our entry into an agreement for a partnering, development or any other transaction, whether commercial, investment or otherwise, that our Board of Directors determines to be material, a change in control of the Company, approval by our Board of Directors of a plan of liquidation or dissolution of the Company, or the exercise of put rights with respect to 100% of the Common Stock outstanding as of June 30, 2011. We will also not be obligated to purchase shares pursuant to properly exercised put rights in the event that we do not have sufficient cash to purchase all such shares. Termination of the put right due to any one of these events could materially and adversely impact on our share price.

Holders of options or warrants to purchase shares of our Common Stock will have to exercise such securities prior to our determination of the put price on June 30, 2011, or such holders will not be eligible to exercise put rights with respect to the shares of Common Stock underlying such securities.

Holders of options or warrants to purchase shares of our Common Stock will have to exercise such securities prior to June 30, 2011, the record date for the put rights, or they will not be eligible to exercise put rights with respect to the shares of Common Stock underlying such securities. If the holder of an option or warrant elects to exercise such security prior to June 30, 2011 in order to take advantage of the put rights associated with the shares underlying such securities, there is no assurance that the put will not terminate pursuant to its terms or that the put price ultimately set by our Board of Directors will exceed the exercise price of any given option or warrant. If the put rights terminate or if the put price is less than the applicable exercise price, the exercising holder would be effectively deprived of any benefit of the put rights.

If we do not have sufficient cash to purchase all shares in respect of which put rights have been properly exercised, we will not be obligated to purchase such shares at all.

The amount of cash available to pay for shares in respect of which put rights have been properly exercised is based in part on the liquidation value of the Company's assets, as determined by the Board of Directors in its sole and absolute discretion. We expect that, if the put rights shall not have terminated by their terms prior to becoming exercisable, our disposable assets (other than cash, cash equivalents and certain investments) will have only limited liquidation value. However, if the Board determines that the liquidation value of such disposable assets is significant, we may not have enough available cash to consummate the purchase of shares in respect of which put rights have been properly exercised, and we are not obligated, nor do we expect, to seek additional debt or equity financing, dispose of assets or take any other actions in order to raise additional funds to consummate the put, or we may be required to utilize a substantial portion of our available cash to consummate the share purchases, which may leave insufficient cash to operate the business for the benefit of the remaining stockholders. We are not obligated, nor do we expect, to undertake a partial purchase of shares subject to put rights under any circumstances.

The exercise of the put rights could result in a change in control of the Company.

If an entity or several entities with substantial holdings on June 30, 2011 do not elect to exercise their put rights, the exercise of the put rights by other stockholders would increase the percentage ownership of the Company for those stockholders who retain their shares, which could result in sufficient ownership by one entity or a small group of entities, such that they could effectively control the Company. Should this occur, it could have a material and adverse impact on our share price and increased uncertainty regarding the future direction of the Company.





Accounting for the put rights could cause variability in the results we report.

The put rights are an embedded equity derivative within our common stock requiring certain fair value measurements at each reporting period. The put rights are a unique addition to the rights of the holders of our common stock and the relevant accounting literature is very complex and the put rights are inherently difficult to value. Additionally, derivative accounting for the put rights also affects the accounting for other items in our financial statements, including our exercisable stock options and warrants, and these affects are inherently difficult to determine, require difficult estimates and are very subjective. We could have substantial variability in the related periodic fair value measurements, which would affect our operating results and in-turn could impact our stock price.

#### Risks Related to Our Common Stock

If we fail to meet the requirements for continued listing on the Nasdaq Capital Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital.

Our common stock was listed on the Nasdaq Global Market and is now listed on the Nasdaq Capital Market. We are required to meet specified financial requirements to maintain our listing on the Nasdaq Stock Markets. One such requirement is that we maintain a minimum bid price of at least \$1.00 per share for our common stock. In 2008, our common stock closed at prices that were below the minimum bid price requirement and on August 11, 2008, we received a notice from Nasdaq, dated August 8, 2008, that the minimum bid price for our common stock had closed under \$1.00 per share for over 30 business days, causing a violation of the continuing listing standard of the Nasdaq Markets. In anticipation of not meeting the Nasdaq Global Market minimum bid price continued listing requirement, we requested and on November 16, 2009, received approval from Nasdaq to transfer the listing of its common stock from the Nasdaq Global Market to the Nasdaq Capital Market. We received a notice on March 4, 2010 from The Nasdaq Stock Market, that we had regained compliance with the Nasdaq Listing Rules for continued listing on the Nasdaq Capital Market.

On May 7, 2010, we received a letter from The Nasdaq Stock Market notifying us that for the 30 consecutive business days preceding the date of the letter, the bid price of our common stock had closed below the \$1.00 per share minimum bid price required for continued inclusion on The Nasdaq Capital Market pursuant to the Nasdaq Listing Rules.

In accordance with Nasdaq Listing Rules, we had 180 calendar days from the date of the Nasdaq letter, or until November 3, 2010, to regain compliance with the minimum bid price rule. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for a minimum of 10 consecutive business days. Nasdaq may, in its discretion, require us to maintain a bid price of at least \$1.00 per share for a period in excess of 10 consecutive business days, but generally no more than 20 consecutive business days, before determining that we have demonstrated an ability to maintain long-term compliance. On November 11, 2010, we received a letter from Nasdaq, notifying us that we had not regained compliance by November 3, 2010 with the Nasdaq Listing Rules.

Nasdaq has determined that as of November 11, 2010, we meet the applicable requirements of Nasdaq Listing Rules, other than the minimum bid price, for continued listing on The Nasdaq Capital Market. Accordingly, we have been afforded an additional period, ending May 2, 2011, to regain compliance with the minimum bid price rule. Our common stock will continue to be listed on the Nasdaq Capital Market during this period. If compliance is not regained, Nasdaq will notify us of its determination to delist our common stock, which decision may be appealed to a Nasdaq Hearing Panel.

We cannot assure you that we will be successful in regaining compliance with the Nasdaq Listing Rules nor maintain compliance in the future. In the event of delisting, trading, if any, could continue to be conducted on the over the

counter market in the so called “pink sheets” or on the OTC Bulletin Board.

Selling our common stock would be more difficult because, among other things, smaller quantities of shares would likely be bought and sold, transactions could be delayed, security analysts' coverage of us could be reduced and shareholders may find it more difficult to obtain accurate quotations as to the market value of our common stock. Also, a delisting (or a notice or other action indicating the possible future delisting of our common stock) could have a material adverse effect on the price for our shares and our ability to issue additional securities or to secure additional financing. In addition, delisting from the Nasdaq Capital Market may subject our common stock to "penny stock" rules under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended. These rules impose additional sales practice and other requirements on broker-dealers who sell and/or make a market in securities deemed penny stocks under SEC rules. Consequently, the delisting of our securities and the applicability of the penny stock rules may adversely affect the liquidity and price of our common stock.

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 \$0.35 during the period of January 1, 2004 through December 31, 2010) 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;
- changes in stock market analyst recommendations regarding us, other drug development companies or the pharmaceutical industry generally;
  - failure in the future to meet the requirements for continued listing on the Nasdaq Capital Market; and
  - the effect or the perceived effect of the stockholder put rights.

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, 2010, there were 40,775,411 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, 2010, we had stock options outstanding to purchase approximately 3,610,173 shares of our common stock, the exercise price of which ranges between \$0.42 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, 2010, 449,502 shares remain available to grant under the 2005 Equity Incentive Plan. In addition, in the event that any future financing or consideration for a future acquisition



should be in the form of, be convertible into or exchangeable for, equity securities, investors will experience additional dilution.

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

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

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

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

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

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

In connection with a Rights Agreement, dated as of June 19, 2007 and as amended May 21, 2010, between us and the Bank of New York, (the "Rights Agreement"), our board approved the designation of 1,000,000 shares of Series A Preferred Stock. The Rights Agreement and the exercise of rights to purchase Series A Preferred Stock pursuant to the terms thereof may delay, defer or prevent a change in control because the terms of any issued Series A Preferred Stock would potentially prohibit our consummation of certain extraordinary corporate transactions without the approval of the Board of Directors. In addition to the anti-takeover effects of the rights granted under the Rights Agreement, the issuance of preferred stock, generally, could have a dilutive effect on our stockholders.

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 believe the facility is well-maintained and adequate for use through the end of our lease term.

Item 3. Legal Proceedings

In April 2009, we became aware of a qui tam complaint that was filed under seal by Jeffrey J. Bierman, as Relator/Plaintiff, on March 28, 2005 in the United States District Court for the District of Massachusetts against us and other companies that allegedly manufactured bone growth stimulation devices, including Orthofix International N.V., Orthofix, Inc., DJO Incorporated, Reable Therapeutics, Inc., the Blackstone Group, L.P., Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., Bioelectron, Inc., LBV Acquisition, Inc., and Smith & Nephew, Inc. By order entered on March 24, 2009, the court unsealed the amended complaint. The amended complaint alleges various causes of action under the federal False Claims Act and state and city false claims acts premised on the contention that the defendants improperly promoted the sale, as opposed to the rental, of bone growth stimulation devices. The amended complaint also includes claims against the defendants for, among other things, allegedly misleading physicians and purportedly causing them to file false claims and for allegedly violating the Anti-kickback Act by providing free products to physicians, waiving patients' insurance co-payments, and providing inducements to independent sales agents to generate business. The Relator is seeking civil penalties under various state and federal laws, as well as treble damages, which, in the aggregate could exceed the financial resources of the Company.

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

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 is awarded the damages sought, we would not be able to continue our business as it is presently conducted.





Item 4. (Removed and Reserved)

## PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

### Market Information

Our common stock commenced trading on Nasdaq on January 28, 1993 and is currently trading on the Nasdaq Capital Market 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.

	2010		2009	
	High	Low	High	Low
First Quarter	\$1.20	\$0.70	\$0.63	\$0.35
Second Quarter	\$1.00	\$0.66	\$0.90	\$0.54
Third Quarter	\$0.97	\$0.63	\$0.95	\$0.55
Fourth Quarter	\$1.23	\$0.45	\$1.04	\$0.60

As of February 28, 2011, 40,775,411 shares of our common stock were outstanding and held by approximately 924 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

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, 2010, 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 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. 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 substantially completed our Phase 2 clinical trial in dermal scarring following shoulder surgery.

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

Years Ended December 31,

	2010	2009(1)	2008	2007	2006(2)	2005(3)	August 5, 2004 to December 31, 2004 (4), (5)
Operating expenses							
General and administrative	\$3,240	\$2,901	\$2,991	\$3,738	\$6,558	\$4,910	\$ 1,878
Research and development	8,168	11,968	10,693	9,641	19,661	25,444	8,080
Purchased in-process research and development	-	-	-	-	8,471	-	25,840
Other	-	-	-	-	-	(250 )	(125 )
Total operating expenses	11,408	14,869	13,684	13,379	34,690	30,104	35,673
Interest and other income, net	(356 )	(737 )	(2,082 )	(3,278 )	(3,883 )	(2,640 )	(751 )
Loss from continuing operations before taxes	11,052	14,132	11,602	10,101	30,807	27,464	34,922
Income taxes expense (benefit)	(181 )	(1,009 )	(363 )		1,106	(108 )	(642 )
Loss from continuing operations	10,871	13,123	11,239	10,101	31,913	27,356	34,280
Discontinued operations							
Net gain on the sale of the bone device business net of taxes \$0, \$0, \$0, \$0, \$96, (\$363) respectively	-	-	-	-	-	(154 )	(2,048 )
<b>NET LOSS</b>	<b>\$10,871</b>	<b>\$13,123</b>	<b>\$11,239</b>	<b>\$10,101</b>	<b>\$31,913</b>	<b>\$27,202</b>	<b>\$ 32,232</b>
Per Share Information:							
Net loss from continuing operations							
basic and diluted	\$0.27	\$0.32	\$0.27	\$0.24	\$0.78	\$0.72	
Net (income) from discontinued operations							
basic and diluted	\$-	\$-	\$-	\$-	\$-	\$-	
Net loss basic and diluted	\$0.27	\$0.32	\$0.27	\$0.24	\$0.78	\$0.72	
Basic and diluted shares outstanding	40,775	40,775	41,078	41,644	40,764	38,032	

1. 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.

2. 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.
3. Total operating expenses in 2005 were reduced by \$250,000 as a result of a final settlement payment received from the buyer of the CPM business. A net gain of \$154,000 was recognized on the sale of the Bone Device Business due to receipt of the entire escrow deposit outstanding.
4. On August 5, 2004, we completed the acquisition of CBI. Capstone expensed in-process research and development and acquisition costs of \$25.8 million.
5. 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,						
	2010	2009	2008	2007	2006	2005	2004
Working capital	\$23,214	\$34,395	\$44,865	\$37,684	\$52,533	\$78,423	\$88,955
Total assets	\$25,288	\$37,135	\$49,514	\$61,862	\$72,589	\$88,343	\$115,184
Potentially redeemable equity	\$15,556	\$-	\$-	\$-	\$-	\$-	\$-
Stockholders' equity	\$7,916	\$34,728	\$47,522	\$59,461	\$69,148	\$84,178	\$110,930

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. We currently own exclusive worldwide rights to Chrysalin.

On February 27, 2006 we purchased certain assets and assumed certain liabilities of AzERx, Inc. Under the terms of the transaction, we acquired an exclusive license for the core intellectual property relating to AZX100, a 24-amino acid synthetic peptide. We have an exclusive worldwide license to AZX100.

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.

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

Our development activities for the Chrysalin and AZX100 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, 2010, we have incurred approximately \$137 million in net losses as a development stage company.





## Shareholder Put Right

In May 2010, our stockholders approved an amendment to our certificate of incorporation, to provide each record holder of our common stock as of June 30, 2011 with the right to require us, under certain circumstances, to purchase for cash all or a portion of the shares of common stock held by such holder at a formula-based price on or about July 31, 2011 (the “put right”). Unless terminated earlier, the put rights will become exercisable by holders of our common stock as of June 30, 2011. We expect to facilitate the exercise of the put rights through the use of a tender offer, informing stockholders of the amount of cash that would be paid for each properly exercised put right and the process by which to exercise such put rights. The cash price to be paid to stockholders for each properly exercised put right will be based on a formula calculated by us as of June 30, 2011, which price is intended to approximate the per-share equivalent of 90% of our available cash (as that term is defined in our Certificate of Incorporation) as of June 30, 2011.

Our obligation to purchase shares upon exercise of the put rights is subject to various conditions. One condition is that such purchases will not violate applicable law, including Section 160 of the Delaware General Corporation Law (DGCL) relating to share repurchases that may impair capital. Because the pending qui tam litigation described in Item 3 above seeks potentially significant damages that, if awarded, could exceed our financial resources, the pendency of this claim at the time of share repurchases pursuant to the put rights could cause the share repurchases to violate Section 160 of the DGCL and the Uniform Fraudulent Transfer Act.

In addition, in determining the price per share to be paid to stockholders upon exercise of the put rights, our Board of Directors must value all contingent liabilities, including the qui tam lawsuit. Our Board of Directors may determine that, even if the probability of an unsuccessful outcome of this litigation is low, the magnitude of the potential damages that may be awarded in an unfavorable verdict is such that the value ascribed to this contingent liability for purposes of the put rights would cause the per share purchase price upon exercise of the put rights to be zero or nearly zero.

In light of the foregoing, we believe that, absent settlement, dismissal or other developments in the qui tam litigation or other changes in circumstance, we may not be able to purchase shares upon exercise of the put rights and the per share purchase price to be determined by the Board for the put rights may be zero.

## Description of the business

Capstone is a biotechnology company committed to developing a pipeline of novel peptides and other molecules aimed at helping patients with under-served conditions. We are focused on the development and commercialization of two product platforms: AZX100 and Chrysalin® (TP508).

### AZX100

AZX100 is a novel synthetic pre-clinical 24-amino acid peptide. AZX100 relaxes smooth muscle, which modulates blood pressure and the function of blood vessels, airways, sphincters, the gastrointestinal tract and the genitourinary tract. Sustained abnormal contraction of any of these muscles is called spasm. Any disorders known to be associated with excessive constriction or inadequate dilation of smooth muscle represent potential applications for AZX100.

AZX100 may also inhibit the fibrotic phenotype of fibroblasts and smooth muscle cells in a mechanism similar to that which causes vasorelaxation. Through phenotypic modulation of fibroblasts and smooth muscle cells, AZX100 may inhibit the scarring that results from wound healing and disease states in the dermis, blood vessels, lungs, liver and other organs.



We are executing a development plan for this peptide which included the filing of an IND for a dermal indication in 2007, completion of Phase 1a and Phase 1b safety studies in 2008, and included the commencement of Phase 2 efficacy studies in dermal scarring in the first quarter of 2009. The first safety study was completed in mid 2008. Our second safety study for dermal scarring (Phase 1b) was completed in the fourth quarter of 2008. During 2010 we completed and reported results for our Phase 2 clinical trials in keloid scar revision. The studies' Safety Committee reviewing all safety-related aspects of the completed clinical trials was satisfied with the profile of AZX100. In 2010 we also substantially completed our Phase 2 clinical trial in dermal scarring following shoulder surgery and we are scheduled to complete and report results on this clinical trial in early 2011.

### Chrysalin

Chrysalin (TP508), a novel synthetic 23-amino acid peptide, is believed to produce angiogenic and other tissue repair effects by activating or upregulating nitric oxide synthase (NOS) and the production of nitric oxide in endothelial cells, and if so, it may have potential therapeutic value in tissues and diseases exhibiting endothelial dysfunction. We have conducted clinical trials for two potential Chrysalin-based products, acceleration of fracture repair, and diabetic foot ulcer. We previously conducted a pilot study for spine fusion. We have conducted pre-clinical testing for cartilage defect repair, cardiovascular repair (including acute myocardial infarction and myocardial ischemia), dental bone repair and tendon repair.

We do not currently plan to re-enter clinical trials with Chrysalin and have focused our efforts on developments, partnering and licensing opportunities.

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### Critical Accounting Policies and Estimates

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

**Income Taxes:** Accounting Standards Codification Topic 740 "Income Taxes" requires that a valuation allowance be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Changes in valuation allowances from period to period are included in the tax provision in the period of change. In determining whether a valuation allowance is required, we take into account all evidence with regard to the utilization of a deferred tax asset, including past earnings history, expected future earnings, the character and jurisdiction of such earnings, unsettled circumstances that, if unfavorably resolved, would adversely affect utilization of a deferred tax asset, carryback and carryforward periods, and tax strategies that could potentially enhance the likelihood of realization of a deferred asset. We have evaluated the available evidence about future taxable income and other possible sources of realization of deferred tax assets and have established a valuation allowance for all of our deferred tax assets of approximately \$52 million at December 31, 2010.

**Patents:** On November 2, 2006, we announced that we have no immediate plans to re-enter clinical trials for Chrysalin-based product candidates and a strategic shift in our development approach to our Chrysalin product platform. We currently intend to pursue development partnering or licensing opportunities for our Chrysalin-based product candidates, a change from its previous development history of independently conducting human clinical trials

necessary to advance our Chrysalin-based product

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candidates to market. Accounting Standards Codification Topic 350 “Intangibles – Goodwill and Other” requires an impairment loss be recognized for an amortizable intangible asset whenever the net cash in-flow to be generated from an asset is less than its carrying cost. We are unable to determine the timing or amount of net cash in-flow to be generated from Chrysalin-based product candidates. Accordingly, due to this uncertainty, we recognized an impairment loss for the amount of unamortized Chrysalin product platform patent costs of \$2,100,000 in 2006. The impairment loss was included in research and development expenses in 2006.

**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 liability classified share-based payments, including grants of stock options, restricted stock units and employee stock purchase rights, to be recorded at fair value. Liability classified awards are to be remeasured at each reporting period with subsequent changes charged to operations. All of our outstanding share-based payments awards are accounted for as liability awards because of the issuance of the put rights. The fair value of liability classified stock option awards is calculated utilizing the Black-Scholes option pricing model as probability weighted for potential put right outcomes. The valuation model utilizes inputs including expected volatility, expected life, risk-free interest rate, expected dividends and probability weighting (Level 3 inputs). We use the historical volatility adjusted for future expectations. The expected life is based on the remaining contractual life of the awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of our awards. The dividend yield assumption is based on our history and expectation of dividend payouts. The probability-weighting is based on expectations as to the outcome of the exercise of the put rights. The fair value of restricted stock awards classified as liabilities are calculated using the then estimated put price determined as defined in our Certificate of Incorporation. Upon settlement, termination or expiration of the put rights, the remaining share based payments awards liability will be reclassified to stockholders’ equity. If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. To the extent that we grant additional equity securities to employees, our stock-based compensation expense will be increased by the additional compensation resulting from those additional grants.

**Put rights:** The put rights are considered embedded equity derivatives under derivative accounting standards. Accordingly, we have bifurcated the estimated fair value of the put rights from the value of our potentially redeemable equity, and recognize subsequent changes in the fair value of the put rights within the statement of operations. We measure the estimated fair value of the put rights based on market transactions which consider the impact of a put right feature within an entity’s common stock at the time of an event that would negatively affect the price of a company’s common stock (Level 3 inputs). The estimated fair value of the put rights also considers the market value of our common stock in relation to the estimated put price at June 2011. At December 31, 2010 the fair value of the put rights was not material.

**Potentially redeemable equity:** The potential obligation at December 31, 2010, created by the put rights, to purchase shares of its common stock, assuming redemption of 100% of the Company’s outstanding shares of common stock at December 31, 2010, and using the estimated put price determined as defined in our Certificate of Incorporation, has been reclassified at December 31, 2010 to potentially redeemable equity. This amount will be adjusted each reporting period to reflect changes in the put right redemption obligation.



#### Results of Operations Comparing Years Ended December 31, 2010 and 2009

**General and Administrative (“G&A”) Expenses:** G&A expenses related to our ongoing development operations were \$3,240,000 for the year ended December 31, 2010 compared to \$2,901,000 in the same period in 2009. Our administrative expenses during 2010 reflect a comparable level of administrative activity in 2009.

**Research and Development Expenses:** Research and development expenses were \$8,168,000 for the year ended December 31, 2010, compared to \$11,968,000 for 2009. Our research and development expenses decreased in 2010, compared to 2009 primarily due to a decrease in AZX100 clinical trial activity, the purchase in 2009 of \$600,000 of peptide and completion in 2009 of our planned partnering or development collaboration research support activities for Chrysalin. Given the overlapping nature of our research efforts it is not possible to clearly separate research expenditures between Chrysalin and AZX100; however, the substantial majority of our research and development expenses in 2010 and 2009 were directed toward AZX100 development efforts.

**Interest and Other Income, Net:** Interest and other income, net decreased from \$737,000 in 2009 to \$356,000 in 2010 due to the decrease in interest rates earned on investments between the two periods and reduction in the amount available for investment. Additionally, 2010 includes a \$244,000 Therapeutic Discovery Project federal grant.

**Net Loss:** We incurred a net loss in the year ended December 31, 2010 of \$10.9 million compared to a net loss of \$13.1 million in 2009. The \$2.2 million decrease in the net loss for 2010 compared to 2009 resulted primarily from a decrease in AZX100 clinical trial activity, the purchase in 2009 of \$600,000 of peptide and completion in 2009 of our planned partnering or development collaboration and research support activities for Chrysalin. This decrease was offset by reduced interest income due to the decrease in interest rates earned on investments between the two periods and reduction in the amount available for investment. Additionally, 2009 included a \$1,009,000 income tax benefit recorded in 2009, due to federal tax legislation passed in 2009, while 2010 included an \$181,000 income tax benefit due to Arizona state tax legislation passed in 2010.

#### Results of Operations Comparing Years Ended December 31, 2009 and 2008

**General and Administrative (“G&A”) Expenses:** G&A expenses related to our ongoing development operations were \$2,901,000 for the year ended December 31, 2009 compared to \$2,991,000 in the same period in 2008. Our administrative expenses during 2009 reflect a comparable level of administrative activity in 2008. Administrative expenses in 2009 were favorably impacted by reduced costs related to the decision by the Securities and Exchange Commission to defer, for one more year, the requirement for the Company to have its independent registered public accountant provide an opinion on the Company’s internal control over financial reporting.

**Research and Development Expenses:** Research and development expenses were \$11,968,000 for the year ended December 31, 2009, compared to \$10,693,000 for 2008. Our research and development expenses increased \$1,275,000 in 2009, compared to 2008 primarily due to an increase in AZX100 clinical trial activity. Given the overlapping nature of our research efforts it is not possible to clearly separate research expenditures between Chrysalin and AZX100; however, the majority of our research and development expenses in 2009 and 2008 were directed toward AZX100 development efforts.

**Interest and Other Income, Net:** Interest and other income, net decreased from \$2,082,000 in 2008 to \$737,000 in 2009 due to the decrease in interest rates earned on investments between the two periods and reduction in the amount available for investment.

**Net Loss:** We incurred a net loss in the year ended December 31, 2009 of \$13.1 million compared to a net loss of \$11.2 million in 2008. The \$1.9 million increase in the net loss for 2009 compared to 2008 resulted primarily from an increase in AZX100 clinical trial activity and reduced





interest income, due to the decrease in interest rates earned on investments between the two periods and reduction in the amount available for investment; partially offset by a \$1,009,000 income tax benefit recorded in 2009, due to federal tax legislation passed in 2009.

### 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 \$93.0 million in cash from the sale of our Bone Device Business. On December 1, 2005, we received the additional \$7.2 million, including interest, from the escrow balance related to the sale of the 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. We also received net proceeds of \$4,612,000 from the exercise of stock options during our development stage period. At December 31, 2010, we had cash and cash equivalents of \$24.4 million.

We announced that we have no immediate plans to re-enter clinical trials for Chrysalin-based product candidates. We currently intend to pursue development collaboration/partnering or licensing opportunities for our AZX100 and Chrysalin-based product candidates. We will continue research and development expenditures for further pre-clinical studies supporting multiple indications for AZX100 and plan to complete our Phase 2 human clinical trial for dermal scarring following shoulder surgery in 2011.

Our future research and development expenses may vary significantly from prior periods depending on the Company's decisions on its future AZX100 and Chrysalin development plans. Our future interest and other income may vary significantly from prior periods based on changes in interest rates and amounts available for investment.

We anticipate that our cash and short-term investments at December 31, 2010 will be sufficient to meet our presently projected cash and working capital requirements for the next year, subject to the effect of any exercise by our stockholders of the Put Rights. However, to complete the clinical trials and supporting research and production efforts necessary to obtain FDA approval for either AZX100 or Chrysalin product candidates would require us to seek other sources of 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.

To the extent, if at all, the Put Rights are exercised at June 30, 2011, our payment of the cash purchase price for the shares tendered may affect our ability to meet our presently projected cash and working capital requirements and our ability to continue operations. To continue operations after the Put Rights are exercised could require us to seek other sources of 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 remaining stockholders' interests.



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. Our investment instruments are classified as held-to-maturity and 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, 2010 and December 31, 2009, 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, 2010, and the statements of operations, potentially redeemable equity, shareholders' equity and cash flows for the period of August 5, 2004 through December 31, 2010, together with the related notes and the report of Ernst & Young, 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, 2010.

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, 2010, 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

John M. Holliman, III (1) Director since 1987

John M. Holliman III, 57, 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.

Augustus A. White, III, MD, Ph.D. (2) (4) Director since 1993

Dr. White, 74, became a director of the Company in July 1993. He is currently the Ellen and Melvin Gordon Distinguished Professor of Medical Education, Professor of Orthopaedic Surgery, and former Master of the Oliver Wendell Holmes Society at the Harvard Medical School and former Professor at the Harvard-MIT Division of Health Sciences and Technology; and Orthopaedic Surgeon-in-Chief, Emeritus, at the Beth Israel Deaconess Medical Center in Boston. Dr. White previously served as the Chief of Spine Surgery at Beth Israel and Director of the Daniel E. Hogan Spine Fellowship Program. He is a graduate of the Stanford University Medical School, holds a Ph.D. from the Karolinska Institute in Stockholm and an A.B. from Brown University, and graduated from the Advanced Management Program at the Harvard Business School. Dr. White is a recipient of the Bronze Star, which he earned while stationed as a Captain in the U.S. Army Medical Corps in Vietnam. He is an internationally known and widely published authority on biomechanics of the spine, fracture healing and surgical and non-surgical care of the spine. He is nationally recognized for his work in medical education, diversity, and issues of health care disparities. Dr. White is a former (retired May 3, 2010) director of Zimmer Holdings, Inc., a publicly held designer, marketer and manufacturer of orthopedic products.



The Board believes Dr. White's education and experience, with particular note of his clinical experience, qualifies him for service on our board and that he brings an important combination of education, real world experience and valuable scientific input to the board.

Fredric J. Feldman, Ph.D. (1) Director since 1991  
(3)

Fredric J. Feldman, Ph.D., 70, has been the President of FJF Associates, a consultant to health care venture capital and emerging companies, since February 1992. 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.

Robert J. Spiegel, MD (2) Director since May 2010  
(3)

Dr. Spiegel, 61, was appointed by the Company's Board of Directors on May 21, 2010 to fill a vacancy (Class I) on the board. Dr. Spiegel has over 25 years of executive-level pharmaceutical development and product commercialization experience with Schering-Plough. Until his retirement in November 2009, Dr. Spiegel held the position of Chief Medical Officer at Schering-Plough and was a member of their Pharmaceutical Leadership Board and Corporate Licensing Review Board; he was also Chairman of Schering-Plough's Safety Review Board and Preparedness Response Committee (Crisis Control). While with Schering-Plough, Dr. Spiegel was involved in the filing of over thirty NDA submissions and interacted with US FDA and EU regulatory authorities on a regular basis, serving on the executive committees overseeing all research projects and drug licensing activities. He also served as the lead Schering-Plough representative in numerous joint venture development projects with biotechnology and other large pharmaceutical partnerships. Dr. Spiegel originally joined Schering-Plough as Director, Clinical Research, progressing through clinical operations as Vice President, Clinical Research, Senior Vice President, Worldwide Clinical Research, becoming Chief Medical Officer in 1998. Dr. Spiegel received his undergraduate degree, cum laude, from Yale University and his MD from the University of Pennsylvania. Dr. Spiegel also serves as a Director on the Boards of Geron Corporation, a publically-held biopharmaceutical company, and Talon Therapeutics, formerly known as Hana Biosciences. He is also a Fellow on the Faculty of the University of Pennsylvania Center for Bioethics.

The Board believes Dr. Spiegel's extensive executive level pharmaceutical development and product commercialization experience qualifies him for service on our board and that he brings important real world experience in all facets of the pharmaceutical development business to the Board.

Elwood D. Howse, Jr. (1) (2) Director since 1987  
(3)

Elwood D. Howse, Jr., 71, 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, now owned by Wells Fargo and 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., Universal Water Group, Inc. and not-for-profits, Junior Achievement Worldwide and Junior Achievement of Washington.



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.

William M. Wardell, MD,  
Ph.D. (4)                      Director since February 2006

Dr. Wardell, 72, has served as a director of the Company since February 2006. He owns and operates the consulting firm Wardell Associates International LLC in Ponte Vedra, FL, where he specializes in drug development, regulatory approval, and safety for a range of pharmaceutical and biotechnology companies. Dr. Wardell has published over one hundred scientific papers and four books, and has testified as an expert in drug development during several Congressional hearings. Dr. Wardell has 22 years of experience in the healthcare industry, holding leadership positions as President, Protein Engineering Corporation (now DYAX); Senior Vice President of Drug Development, Parke-Davis; Vice President and Medical Director, Boehringer Ingelheim Pharmaceuticals; Senior Scientific Officer, Covance; and Executive Director of the Covance Institute for Drug Development Sciences. During his tenure at these companies, Dr. Wardell was responsible for 11 approved New Drug Applications and overall he has had a role in the development and approval of over thirty now-marketed drugs. He previously served as an associate professor of Pharmacology, Toxicology and Medicine, attending on the Clinical Pharmacology consultation service of Strong Memorial Hospital at the University of Rochester Medical Center, where he co-founded and directed the University's Center for the Study of Drug Development (now at Tufts). Dr. Wardell earned his MA, Ph.D. in Pharmacology, and MD at the University of Oxford (UK), and was a Merck International Fellow in Clinical Pharmacology and Medicine under Dr. Louis Lasagna at the University of Rochester / Strong Memorial Hospital.

The Board believes Dr. Wardell's education and experience, with particular note of Dr. Wardell's pharmaceutical development experience and success, brings important operating and scientific input to the Board and qualifies him for service on our Board.

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- (1)                                      Member of the Executive Committee.
- (2)                                      Member of the Audit Committee.
- (3)                                      Member of the Compensation Committee.
- (4)                                      Member of the Corporate Governance/Nominating Committee

The Audit Committee, which is a separately-designated standing committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), consists of Mr. Howse (Chairman), Dr. White and Dr. Spiegel, who replaced Dr. Feldman in August 2010.

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 following table sets forth information regarding our executive officers:

Name	Age	Title
John M. Holliman, III	57	Executive Chairman and Principal Executive Officer
Randolph C. Steer, MD, Ph.D.	61	President
Les M. Taeger	60	Senior Vice President, Chief Financial Officer and Principal Financial and Accounting Officer
Dana B. Shinbaum	48	Vice President, Business Development

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. Dr. Steer has been an independent pharmaceutical, biotechnology and medical devices consultant since 1989, and has provided consulting 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.

Dana B. Shinbaum joined the Company as Vice President of Business Development in October 2005. Previously he served as Vice President, Product Planning and Market Analytics at Savient Pharmaceuticals, Inc., and has over twenty years of experience in the pharmaceutical/biotechnology industry. While at Savient his responsibilities included creating and developing new business opportunities, leading global project teams and managing product launches. He played key strategic



planning roles in Savient's acquisition of Rosemont Pharmaceuticals Ltd. and the divestiture of Bio-Technology General Ltd., Savient's global biologics business. Prior to joining Savient, Mr. Shinbaum was at Wyeth-Ayerst Laboratories, where he held market planning and marketing roles of increasing responsibility, including Product Manager for the PREMARIN® franchise. Mr. Shinbaum received a Master of Business Administration, summa cum laude, from Drexel University in Philadelphia and a Bachelor of Arts degree from Lafayette College in Easton, Pennsylvania.

#### CORPORATE GOVERNANCE AND CODE OF ETHICS

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

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

#### SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Under the securities laws of the United States, the Company's directors, its executive officers and any persons holding more than 10% of the Company's Common Stock are required to report their initial ownership of the Company's Common Stock and any subsequent changes in that ownership to the SEC. Specific due dates for these reports have been established, and the Company is required to disclose any failure to file by these dates. The company believes that all of these filing requirements were satisfied during the year ended December 31, 2010.

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 (\$) <sup>(1)</sup>	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Fredric J. Feldman, Ph.D. Director	64,000	-	4,000	-	-	-	68,000
Elwood D. Howse, Jr. Director	63,000	-	4,000	-	-	-	67,000
Robert J. Spiegel, MD Director	23,000	-	21,000	-	-	-	44,000
William M. Wardell, MD, Ph.D. Director	64,000	-	10,000	-	-	-	74,000
Augustus A. White, III, MD, Ph.D. Director	62,000	-	4,000	-	-	-	66,000

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

During the year ended December 31, 2010, the Company paid directors an annual retainer of \$24,000, payable quarterly in advance, \$2,500 for each board meeting attended in person and \$1,000 for each board meeting attended by telephone. 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 \$0.72 per share on January 1, 2010 (fair value of \$4,000). On May 21, 2010, the Company granted non-qualified stock options to Dr. Spiegel (50,000 shares) and Dr. Wardell (15,000 shares) at a price of \$0.82 per share (fair value of \$21,000 and \$6,000, respectively). 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.

On June 10, 2005 the Board of Directors also approved an annual award to each director of \$25,000 of restricted stock. The shares granted vest one year from the date of issuance. On January 1, 2010 the Board paid each director \$25,000 in lieu of the annual stock award.



## Director Outstanding Equity Awards at Fiscal Year-End

Name	Option Awards			Options Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)		
(a)	(b)	(c)	(d)	(e)	(f)
John M. Holliman, III	20,000			3.58	8/24/2011
	200,000			1.75	5/12/2016
	50,000			1.02	2/21/2018
	* 114,583	10,417		0.45	2/3/2019
	* 41,667	58,333		0.82	2/4/2020
Robert J. Spiegel, MD	50,000			0.82	5/21/2020
William M. Wardell, MD, Ph.D.	10,000			5.33	2/11/2016
William M. Wardell, MD, Ph.D.	15,000			0.82	5/21/2020
Various directors:					
(1) (2) (3) (5)	30,000			3.19	1/19/2011
(1) (2) (3) (5)	25,000			3.93	10/26/2011
(1) (2) (3) (5)	5,000			4.89	12/31/2011
(1) (2) (3) (5)	10,000			3.61	12/31/2012
(1) (2) (3) (5)	10,000			6.13	12/31/2013
(1) (2) (3) (5)	30,000			7.40	1/23/2014
(1) (2) (3) (5)	10,000			6.25	12/31/2014
(1) (2) (3) (5)	10,000			4.90	1/2/2016
(1) (2) (3) (4) (5)	25,000			1.75	5/12/2016
(1) (2) (3) (4) (5)	10,000			1.43	1/1/2017
(1) (2) (3) (4) (5)	10,000			1.35	1/1/2018
(1) (2) (3) (4) (5)	** 13,542	11,458		0.70	10/30/2018
(1) (2) (3) (4) (5)	10,000			0.42	1/1/2019
(1) (2) (3) (4) (5)	10,000			0.72	1/1/2020
Feldman, Fred (1)	* Vest monthly over a two-year period ending 2/21/2010 and 2/3/2011				
Holliman, John (2)	** Vest monthly over a four-year period ending 10/30/2012				
Howse, Elwood (3)	All other directors options were fully vested on 12/31/2010				
Wardell, William (4)					
White, Augustus (5)					





## EXECUTIVE COMPENSATION

### COMPENSATION DISCUSSION AND ANALYSIS

#### Compensation Philosophy

The objectives of the Company's executive compensation policies are to attract, retain and reward executive officers who contribute to the Company's success, to align the financial interests of executive officers with the performance of the Company, to strengthen the relationship between executive pay and shareholder value, to motivate executive officers to achieve the Company's business objectives and to reward individual performance. The Company used base salary, cash bonuses, stock awards and stock options to achieve these objectives.

#### Review of Current Compensation Components of Executive Chairman and other Executive Officers

The Compensation Committee reviews all components of the Executive Chairman's and other executive officers' compensation, including salary, bonus, stock awards, accumulated vested and unvested stock options, the dollar value to the executive and cost to the company of all perquisites and other personal benefits, as well as the actual projected payout obligations under several potential severance and change-in-control scenarios and any limitations on the deductibility for federal income tax purposes of all compensation. The Compensation Committee considers the following:

- 1) Each executive has individual performance goals for the fiscal year. The Compensation Committee reviews the performance goals and expectations for individual executive positions. Based on recommendations from the Executive Chairman and the Compensation Committee's evaluation of the performance achievement of these goals, the Compensation Committee determines the resulting bonus and/or changes to salary components for the executive officers. The Executive Chairman also recommends individual performance objectives for himself for each fiscal year. The Compensation Committee approves the performance objectives of the Executive Chairman and evaluates the Executive Chairman's performance measured against these objectives and evaluates and formulates any potential changes in compensation accordingly.
- 2) The Company's performance is compared against the goals for the fiscal year. Strategic, high level performance expectations are identified each fiscal year for the Company. The Executive Chairman provides documentation to the Compensation Committee regarding the expectations and corresponding results of operations.
- 3) The level of compensation for executives in similar positions for companies of similar size and development structure is considered in determining executive compensation. To enable the Company to continue to attract and retain executives in the competitive marketplace, executive compensation for similar companies is reviewed. The Company typically obtains this data through a review of publicly available executive compensation information for comparable public companies.

#### The Compensation Committee's Conclusion

Based on the review detailed above, 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 with this proxy statement. Overall our compensation decisions are framed by the nature of our business as a development stage pharmaceutical company with the need for highly specialized and talented individuals. Our compensation policies are designed to take into account the fact that the competition for executives is with all sizes of pharmaceutical and biotech firms and must factor in not just comparable compensation, including health care, retirement or other traditional executive benefits, but issues such as location and position stability. We operate in Tempe, Arizona, a relatively small market for biotechnology, and in a field with substantial product development risks, with no current revenue and limited funds.

## Annual Base Compensation and Cash Bonus

As previously mentioned, each executive officer receives a base salary and a cash bonus which is based on performance against both Company and individual performance goals. We have established base salaries which we believe are comparable to other biotechnology firms and with the potential cash bonus, provide for a reasonable level of cash-based compensation to the executives. Base compensation in 2010 ranged from \$325,000 for Dr. Steer, to \$200,000 for Mr. Holliman. Executive officers did not receive an increase in base pay in 2010. No executive salary increases are planned for 2011. In 2010 the bonus potential was 40% of base salary for Mr. Holliman, Dr. Steer, Mr. Taeger and Mr. Shinbaum. Mr. Holliman elected to not accept a bonus for 2010. The bonus plan placed 25-30% of the executive's cash compensation at risk, which we believe is a reasonable level of risk for cash-based compensation. In 2010, performance for the bonus plan was weighted 70% towards Company goals and 30% towards individual goals. Company and individual goals included a combination of operating, such as timely completion of clinical or pre-clinical tasks and performance against our strategic plan, financial, such as performance to budget or generation of unbudgeted cost savings, and administrative, such as maintaining compliance with Securities and Exchange Commission rules, regulations and reporting requirements. We believe that the cash compensation at risk and the performance goals of the 2010 bonus plan serve to align our executives' interests with our interests and focus their efforts where we believe they have the potential to achieve performance we have identified as important to accomplishing objectives necessary to advance our development efforts.

## Equity Based Compensation

As previously discussed, 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, both during the employment offer process and annually, to generate a commitment to and a long-term investment in our Company. Grants and awards connected with employment offers were determined based on the position and competitive factors at the time of the offers. Grants and awards are targeted such that an annual \$1 increase in market price, currently an annual \$41,000,000 increase in shareholder value, would provide approximately 10% to 20% of the executive's compensation. We believe grants at these levels serve to gradually increase our executives' commitment to the Company and align their interests with other stockholders of the Company.



### Stock Option Grants

As part of our long-term incentives we grant options to purchase shares of our Common Stock to our executives. During 2010, the Company granted options to employees to purchase 324,000 shares of the Company's Common Stock with the exercise price determined by the closing market price on the date of grant (\$0.82). This grant included grants to the named executives (Holliman 100,000 shares, Steer 50,000 shares, Taeger 35,000 shares and Shinbaum 35,000 shares).

On January 19, 2011, the Company granted options to employees to purchase 150,000 shares of the Company's Common Stock with the exercise determined by the closing market price on the date of grant (\$0.67). This grant included grants to the named executives (Steer 50,000 shares, Taeger 25,000 shares and Shinbaum 25,000 shares).

### Common Stock Awards

We believe common stock awards are an important element in our compensation plan, however, in 2010 there were no common stock awards. On January 19, 2011, Mr. Holliman was awarded 50,000 shares of restricted stock with a fair value of \$34,000 on the date of award.

### Fringe Benefits, Perquisites and Retirement Benefits.

Our executives participate in group health, dental, life, and disability programs and participate 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.

## REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS

The Compensation Committee of the Company's Board of Directors (the "Compensation Committee") recommends the compensation of the Executive Chairman and President to the Board and reviews and approves the design, administration and effectiveness of compensation programs for other key executive officers, including salary, cash bonus levels, other perquisites and stock awards or option grants under the Company's stock option plans. The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis with management, and based on this review and discussion, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K.

### Compensation Committee during 2010:

Fredric J. Feldman, Ph.D. (Chairman)  
Elwood D. Howse, Jr.  
Robert J. Spiegel, MD (joined committee August 2010)

## COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

None

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## SUMMARY COMPENSATION TABLE

The following table sets forth, with respect to the years ended December 31, 2010, 2009 and 2008, compensation awarded to, earned by or paid to the Company's principal executive officer, principal financial officer and each of the two most highly compensated executive officers other than the principal executive officer and the principal financial officer, who were serving as executive officers at the end of the last completed fiscal year (the "named executive officers").

Name	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
John M. Holliman, III Executive Chairman (Principal Executive Officer)	2010	200,000	-	-	50,000(1)	-	-	64,000(1)	314,000
	2009	200,000	-	-	42,000(1)	-	-	62,000(1)	304,000
	2008	200,000	-	25,000(1)	57,000(1)	-	-	36,000(1)	318,000
Randolph C. Steer, MD, Ph.D. President	2010	325,000	88,000	-	23,000	-	-	-	436,000
	2009	325,000	75,000	-	18,000	-	-	-	418,000
	2008	325,000	89,000	-	26,000	-	-	-	440,000
Les M. Taeger Chief Financial Officer (Principal Financial Officer)	2010	242,000	68,000	-	16,000	-	-	-	326,000
	2009	242,000	56,000	-	12,000	-	-	-	310,000
	2008	242,000	82,000(2)	-	8,000	-	-	-	332,000
Dana B. Shinbaum VP Business Development	2010	242,000	68,000	-	16,000	-	-	-	326,000
	2009	242,000	51,000	-	12,000	-	-	-	305,000
	2008	242,000	77,000(2)	-	7,000	-	-	-	326,000

(1) Mr. Holliman is a member of the Board of Directors and as a director, received compensation of \$64,000, \$62,000 and \$36,000, in cash, in 2010, 2009 and 2008, respectively, a stock award in 2008 with a fair value of \$25,000 on

the date of the award, 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 \$68,000, \$74,000 and \$67,000 in 2010, 2009 and 2008, 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 2010, in Note 5 to the Financial Statements included in this Annual Report on Form 10-K, for 2009, in Note 6 to our Annual Report on form 10-K filed with the Securities and Exchange Commission on March 12, 2010, and for 2008, in Note 6 to the Annual Report on form 10-K/A filed with the Securities and Exchange

Commission on September 18, 2009.

(2) In 2008, Mr. Taeger and Mr. Shinbaum were awarded 14,706 and 12,255 shares, respectively, with a fair value of the share awards on the date of grant of \$15,000 and \$12,500, respectively. These amounts are included in the “Bonus” column.

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

#### 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)	(l)
John M. Holliman, III Executive Chairman	1/1/10	-	10,000	0.72	4,000
	2/4/10	-	100,000	0.82	46,000
		-			
Randolph C. Steer, MD, Ph.D. President	2/4/10	-	50,000	0.82	23,000
Les M. Taeger Chief Financial Officer	2/4/10	-	35,000	0.82	16,000
Dana B. Shinbaum VP Business Development	2/4/10	-	35,000	0.82	16,000



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

## OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

Name	Option Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
(a)	(b)	(c)	(e)	(f)
<b>John M. Holliman, III</b>				
	30,000	-	3.19	1/19/2011
	20,000	-	3.58	8/24/2011
	25,000	-	3.93	10/26/2011
	5,000	-	4.89	12/31/2011
	10,000	-	3.61	12/31/2012
	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
*	13,542	11,458	0.70	10/30/2018
	10,000	-	0.42	1/1/2019
**	114,583	10,417	0.45	2/3/2019
	10,000	-	0.72	1/1/2020
**	41,667	58,383	0.82	2/4/2020
<b>Randolph C. Steer, MD, Ph.D.</b>				
	200,000	-	1.75	5/12/2016
	50,000	-	1.53	5/21/2017
	50,000	-	1.02	2/21/2018
**	68,750	6,250	0.45	2/3/2019
**	20,833	29,167	0.82	2/4/2020
<b>Les M. Taeger</b>				
	150,000	-	5.15	1/16/2016
	150,000	-	1.70	6/2/2016
***	10,417	4,289	1.02	2/21/2018
**	45,833	4,167	0.45	2/3/2019
**	14,583	20,417	0.82	2/4/2020
<b>Dana B. Shinbaum</b>				
	50,000	-	3.27	10/29/2015
	35,000	-	5.39	1/30/2016
	150,000	-	1.70	6/2/2016
***	8,681	3,574	1.02	2/21/2018
**	45,833	4,167	0.45	2/3/2019
**	14,583	20,417	0.82	2/4/2020

\* Vesting monthly over four years

\*\* Vesting over two  
years monthly

\*\*\* Vesting over four  
years monthly

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

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

Under the Holliman Agreement, Mr. Holliman's services to the Company may be terminated by the Company at any time, with or without cause. In the event of termination without cause, payments under the Holliman Agreement will continue for twelve months after the date of termination. It provides for annual base cash compensation of \$200,000, payable in accordance with the Company's standard payroll practices and a target bonus of 40% of base compensation upon the achievement of individual and corporate performance objectives. In addition, the Holliman Agreement includes other terms and conditions consistent with agreements entered into with other Company executives.

In the event of a change of control or liquidation of the Company, the vesting of the options to purchase shares of the Company's common stock held by Mr. Holliman, will be accelerated so that the options will become fully exercisable.

Effective April 5, 2006, Randolph C. Steer, MD, Ph.D., became President of the Company. Dr. Steer has performed consulting services for the Company since 2002. On May 12, 2006, the Company also entered into an agreement with Randolph C. Steer, MD, Ph.D., to compensate Dr. Steer for his services as the Company's President and Chief Operating Officer (the "Steer Agreement"). Under the Steer Agreement, Dr. Steer's services to the Company may be terminated by the Company at any time, with or without cause. If the event of termination is without cause, payments under the Steer Agreement will continue for twelve months after the date of termination. Dr. Steer's annual base cash compensation is \$325,000, payable in accordance with the Company's standard payroll practices. Dr. Steer is also eligible for a target bonus of 40% of base compensation upon the achievement of individual and corporate performance objectives. In addition, the Steer Agreement includes other terms and conditions consistent with agreements entered into with other Company executives.

In the event of a change of control or liquidation of the Company, the vesting of the options to purchase shares of the Company's common stock held by Dr. Steer, will be accelerated so that the options will become fully exercisable.

On January 10, 2006, the Company entered into an employment agreement with Les M. Taeger, dated as of January 10, 2006, effective as of January 16, 2006 (the "Taeger Employment Agreement"), pursuant to which Mr. Taeger serves as the Company's Senior Vice President / Chief Financial Officer. Under the Taeger Employment Agreement, Mr. Taeger may be terminated at any time, with or without cause, at the option of either the Company or Mr. Taeger. If the Company terminates Mr. Taeger without cause, provided Mr. Taeger first executes a Severance Agreement in the form then used by the Company, the Company shall continue to pay to Mr. Taeger his minimum base salary in effect at the time of termination for a period of one year following the date of termination, at the time and in the manner dictated by the Company's standard payroll policies. Should such termination occur as a result of a Change in Control, the Company shall also pay Mr. Taeger a pro-rata share of his bonus at the time of termination. Mr. Taeger's annual base salary is \$242,000. Mr. Taeger is eligible to participate in the Company's discretionary bonus program, which provides for a bonus of up to 40% of his base salary, and Mr. Taeger will receive medical, dental and other fringe benefits generally granted to the Company's senior management.

On October 17, 2005, the Company entered into an employment agreement with Dana B. Shinbaum (the “Shinbaum Employment Agreement”), pursuant to which Mr. Shinbaum serves as the Company’s Vice President of Business Development and Strategic Marketing. Under the Shinbaum Employment Agreement, Mr. Shinbaum may be terminated at any time, with or without cause, at the option of either the Company or Mr. Shinbaum. If the Company terminates Mr. Shinbaum without cause, provided Mr. Shinbaum first executes a Severance Agreement in the form then used by the Company, the Company shall continue to pay to Mr. Shinbaum his minimum base salary in effect at the time of termination for a period of one year following the date of termination, at the time and in the manner dictated by the Company’s standard payroll policies. Should such termination occur as a result of a Change in Control, the Company shall also pay Mr. Shinbaum a pro-rata share of his bonus at the time of termination. Mr. Shinbaum’s annual base salary is \$242,000. Mr. Shinbaum is eligible to participate in the Company’s discretionary bonus program, which provides for a bonus of up to 40% of his base salary, and Mr. Shinbaum will receive medical, dental and other fringe benefits generally granted to the Company’s senior management.

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

At December 31, 2010, unvested options held by named executive officers had intrinsic value of \$7,000 and, accordingly, accelerated vesting clauses if triggered at December 31, 2010, would have provided \$7,000 additional compensation to the named executive officers.

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

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of the Company’s Common Stock at February 28, 2011 with respect to (i) each person known to the Company to own beneficially more than five percent of the outstanding shares of the Company’s Common Stock, (ii) each director of the Company, (iii) each of the named executive officers and (iv) all directors and executive officers of the Company as a group. At February 28, 2011 there were 40,775,411 shares of the Company’s Common Stock outstanding.

Beneficial Owner	Common Stock	
	Beneficially Owned (1)	
	Number	Percent of Class
Fredric J. Feldman (2)	381,189	*
John M. Holliman, III (3)	921,230	2.2
Elwood D. Howse, Jr. (4)	403,328	*
Robert J. Spiegel (5)	60,000	*
William M. Wardell (6)	266,327	*
Augustus A. White, III (7)	378,502	*
Randolph C. Steer (8)	455,715	1.1
Les M. Taeger (9)	429,759	1.0
Dana B. Shinbaum (10)	362,056	*
BVF Group (11)	5,470,388	13.4
All directors and executive officers as a group (12)	3,658,106	8.2

\* Less than one percent

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

(2) Includes 190,625 shares Dr. Feldman has a right to acquire upon exercise of stock options. Voting and investment power shared with spouse.

(3) Includes 643,958 shares Mr. Holliman has a right to acquire upon exercise of stock options, 3,000 shares indirectly owned as trustee and 1,658 shares indirectly owned as trustee of Valley Ventures III, LP.

(4) Includes 190,625 shares Mr. Howse has a right to acquire upon exercise of stock options.

(5) Includes 60,000 shares Dr. Spiegel has a right to acquire upon exercise of stock options.

(6) Includes 115,625 shares Dr. Wardell has a right to acquire upon exercise of stock options.

(7) Includes 190,625 shares Dr. White has a right to acquire upon exercise of stock options and 8,846 shares held in the White Trust and beneficially owned by Dr. White.

(8) Includes 410,417 shares Dr. Steer has a right to acquire upon exercise of stock options.

(9) Includes 385,185 shares Mr. Taeger has a right to acquire upon exercise of stock options.

(10) Includes 385,185 shares Mr. Shinbaum has a right to acquire upon exercise of stock options.

(11) BVF Group (Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P. BVF Investments, L.L.C., Investment 10, L.L.C., BVF Partners, L.P., BVF Inc.) is not a related party or otherwise affiliated with the

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Company, its directors or officers, and the principal business office of the Reporting Persons comprising the Group is located at 900 North Michigan Avenue, Suite 1100, Chicago, IL 60611.

- (12) Includes 2,505,305 shares directors and executive officers have a right to acquire upon exercise of stock options.

The address of each of the listed stockholders, unless noted otherwise, is in care of Capstone Therapeutics Corp., 1275 West Washington Street, Suite 101, Tempe, AZ 85281.

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## EQUITY COMPENSATION PLANS

The following provides tabular disclosure of the number of securities to be issued upon the exercise of outstanding options, the weighted average exercise price of outstanding options, and the number of securities remaining available for future issuance under equity compensation plans as of December 31, 2010, aggregated into two categories - plans that have been approved by stockholders and plans that have not. See Note 6 to the financial statements included in this Annual Report on Form 10-K for additional information on our equity compensation plans.

Plan Category:	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(c)	(b)	(c)
Equity Compensation Plans approved by Security Holders	3,610,173	\$ 2.32	449,052
Equity Compensation Plans not approved by Security Holders	N/A	N/A	N/A
Total	3,610,173	\$ 2.32	449,052

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

The Board of Directors is composed of five outside directors that are independent directors under Nasdaq Listing Rule 5605(a)(2). On April 5, 2006, Mr. Holliman became Executive Chairman and Principal Executive Officer of the Company and is no longer an independent director under Nasdaq Listing Rule 5605(a)(2).

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The Board of Directors reviews transactions with related parties, but has no formal policies in place with respect to such reviews or the approval of such transactions. During 2010 there were no reported related party transactions with directors, executive officers or other related parties, which might have required disclosure under SEC rules or which were otherwise material to the Company.

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

## Item 14. Principal Accountant Fees and Services

The following table sets forth the aggregate fees billed to the Company for the years ended December 31, 2010 and December 31, 2009 by our principal accounting firm Ernst & Young LLP.

Type of Fee	Amount	
	2010	2009
Audit Fees (1)	\$177,000	\$174,000
Audit-Related Fees (2)	-	3,000



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Total Audit and Audit-Related Fees	177,000	177,000
Tax Fees (3)	-	-
All Other Fees (4)	-	-
Total Fees	\$177,000	\$177,000

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- (1) Audit fees include fees for services rendered in connection with the audits of the Company's financial statements for the fiscal years ended December 31, 2010 and 2009 and reviews of the financial statements included in the Company's quarterly reports on Form 10-Q during the applicable fiscal year.
- (2) Audit-related fees would include fees for services rendered for matters such as a business combination, sales of shares of the Company's common stock, and responses to accounting and reporting-related matters.
- (3) Tax fees would include fees for services rendered for tax compliance, preparation of original and amended tax returns, claims for refunds and other tax services.
- (4) Our principal accounting firm did not perform nor bill the Company for any other services during the fiscal years ended December 31, 2010 and 2009 that are appropriately classified as "All Other Fees."

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

Consistent with the rules of the Securities and Exchange Commission regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation for, and overseeing the work of, the independent auditor. In recognition of this responsibility, the Audit Committee has included in its charter the responsibility to pre-approve "all auditing services and permitted non-auditing services proposed to be performed by the independent auditor, subject to the de minimis exceptions for non-audit services that were not recognized as non-audit services at the time of engagement and which are subsequently approved by the committee prior to completion of the audit." No fees were paid to the independent auditor pursuant to the "de minimis" exception to the foregoing pre-approval policy in 2010.

#### PART IV

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

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

1. Financial Statements.

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

Report of Independent Registered Public Accounting Firm.

Balance Sheets - December 31, 2010 and 2009.

Statements of Operations - Each of the years in the two-year period ended December 31, 2010 and for the period of August 5, 2004 through December 31, 2010.

Statements of Potentially Redeemable Equity and Stockholders' Equity - Each of the years in the two-year period ended December 31, 2010 and for the period of August 5, 2004 through December 31, 2010.

Statements of Cash Flows - Each of the years in the two-year period ended December 31, 2010 and for the period of August 5, 2004 through December 31, 2010.

Notes to Financial Statements.

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

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

(b) Exhibits

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

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

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SIGNATURES

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

CAPSTONE THERAPEUTICS  
CORP.

Date: March 29, 2011

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

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

Signature	Title	Date
/s/ John M. Holliman, III John M. Holliman, III	Executive Chairman (Principal Executive Officer) and Director	March 29, 2011
/s/ Fredric J. Feldman Fredric J. Feldman, Ph.D.	Director	March 29, 2011
/s/ Elwood D. Howse, Jr. Elwood D. Howse, Jr.	Director	March 29, 2011
/s/ Robert J. Spiegel Robert J. Spiegel, MD	Director	March 29, 2011
/s/ William M. Wardell William M. Wardell, MD, Ph.D.	Director	March 29, 2011
/s/ Augustus A. White, III Augustus A. White III, MD, Ph.D.	Director	March 29, 2011
/s/ Randolph C. Steer Randolph C. Steer, MD, Ph.D.	President	March 29, 2011
/s/ Les M. Taeger Les M. Taeger	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2011



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Capstone Therapeutics Corp. (“the Company”)  
(Formerly OrthoLogic Corp.)  
Exhibit Index to Annual Report on Form 10-K  
For the Year Ended December 31, 2010

Exhibit No.	Description	Incorporated by Reference To:	Filed Herewith
2.1	Asset Purchase Agreement and Plan of Reorganization by and between OrthoLogic Corp. and Chrysalis Biotechnology, dated April 28, 2004 (*)	Exhibit 2.1 to the Company’s Registration Statement on Form S-4 filed with the SEC on June 3, 2004 (“June 2004 S-4”)	
2.2	Amendment No. 1 to Asset Purchase Agreement and Plan of Reorganization by and between OrthoLogic Corp. and Chrysalis Biotechnology, dated June 1, 2004 (*)	Exhibit 2.2 to the Company’s June 2004 S-4	
2.3	Amendment No. 2 to Asset Purchase Agreement and Plan of Reorganization between OrthoLogic Corp. and Chrysalis Biotechnology, Inc., dated August 5, 2004 (*)	Exhibit 2.1 to the Company’s Current Report on Form 8-K filed on August 6, 2004	
2.4	Asset Purchase Agreement and Plan of Reorganization by and between OrthoLogic Corp. and AzERx, Inc., dated February 23, 2006 (*)	Exhibit 10.1 to the Company’s Registration Statement on Form S-3 filed with the SEC on April 25, 2006	
3.1	Amended and Restated Certificate of Designation of Series A Preferred Stock, executed June 19, 2007	Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on June 25, 2007 (“June 25th 2007 8-K”)	
3.2	Bylaws of the Company	Exhibit 3.4 to the Company’s Amendment No. 2 to Registration Statement on Form S-1 (No. 33-47569) filed with the SEC on January 25, 1993 (“January 1993 S-1”)	
3.3	Certificate of Incorporation, as amended through May 21, 2010	Exhibit 3.1 to the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2010, filed with the SEC on August 9, 2010	
4.1	Class A Warrant Agreement dated February 24, 2006, between OrthoLogic Corp. and PharmaBio Development Inc. (d/b/a NovaQuest)	Exhibit 4.1 to the Company’s Current Report on Form 8-K filed with the SEC on March 3, 2006	
4.2	Class A Warrant Agreement dated June 30, 2006 by and between	Exhibit 4.1 to the Company’s Current Report on Form 8-K filed with the SEC on	

OrthoLogic Corp. and PharmaBio July 6, 2006  
Development Inc

- 4.3 Amended and Restated Class C Warrant Agreement dated February 24, 2006, and amended and restated as of June 30, 2006, related to the Common Stock and Warrant Purchase Agreement by and between OrthoLogic Corp. and PharmaBio Development Inc. Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, filed with the SEC on May 7, 2007.
- 4.4 Amended and Restated Class D Warrant Agreement dated February 24, 2006, and amended and restated as of June 30, 2006, related to the Common Stock and Warrant Purchase Agreement by and between OrthoLogic Corp. and PharmaBio Development Inc. Exhibit 4.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2007, filed with the SEC on March 5, 2008.

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4.5	Rights Agreement, dated as of June 19, 2007, between OrthoLogic Corp. and the Bank of New York	Exhibit 4.1 to the June 25th 2007 8-K
4.6	First Amendment to Rights Agreement dated as of May 21, 2010, between Capstone Therapeutics Corp. and the Bank of New York Mellon	Exhibit 4.1 to the Company's Current Report on form 8-K, filed with the SEC on May 25, 2010.
4.7	Amended and Restated Class B Warrant Agreement dated February 24, 2006, and amended and restated as of June 30, 2006, between OrthoLogic Corp. and PharmaBio Development Inc. (d/b/a NovaQuest) (asterisks located within exhibit denote information that has been redacted pursuant to a request for confidential treatment filed with the SEC)	Exhibit 4.4 to the Company's Amendment No. 1 to Registration Statement on Form 8-A/A , filed with the SEC on May 25, 2010.
10.1	Form of Indemnification Agreement(**)	Exhibit 10.16 to the Company's January 1993 S-1
10.2	1997 Stock Option Plan of the Company, as amended and approved by the stockholders (1)	Exhibit 4.3 to the Company's Registration Statement on Form S-8, filed with the SEC on March 2, 2005
10.3	Patent License Agreement between the Board of Regents of The University of Texas System through its component institution The University of Texas Medical Branch at Galveston and Chrysalis Biotechnology, Inc., dated April 27, 2004 and exhibits thereto (2)	Exhibit 10.1 to the Company's Amendment No. 1 to its Registration Statement on Form S-4, filed July 14, 2004
10.4	Form of Incentive Stock Option Grant Letter for use in connection with the Company's 1997 Stock Option Plan (***)	Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 4, 2005
10.5	Form of Non-qualified Stock Option Grant Letter for use in connection with the Company's 1997 Stock Option Plan (***)	Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 19, 2006
10.6	Patent Assignment Agreement dated June 28, 2005, between the Company and the University of Texas	Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2005, filed with the SEC on August 9, 2005 (the "June 2005 10-Q")
10.7	Director Compensation Plan, effective June 10, 2005 (1)	Exhibit 10.2 to the June 2005 10-Q
10.8	Employment Agreement between the Company and Dana Shinbaum, dated October 17, 2005 (1)	Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 27, 2005
10.9	Employment Agreement dated January 10, 2006 between the Company and Les M. Taeger (1)	Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 11, 2006 (the "January 11th 8-K")
10.10	Intellectual Property, Confidentiality and Non-Competition Agreement between the Company and Les M. Taeger dated	Exhibit 10.2 to the January 11th 8-K

January 10, 2006 (1)		
10.11	Common Stock and Warrant Purchase Agreement by and between OrthoLogic Corp. and PharmaBio Development Inc., dated February 24, 2006.	Exhibit 10.1 to the Company's April 2006 S-3
10.12	Registration Rights Agreement by and between OrthoLogic Corp. and PharmaBio Development Inc., dated February 24, 2006	Exhibit 4.8 to the Company's Amendment No. 1 to Registration Statement on Form 8-A/A , filed with the SEC on May 25, 2010.

10.13	Registration Rights Agreement by and between OrthoLogic Corp., AzERx, Inc., and Certain Shareholders, dated February 27, 2006	Exhibit 10.3 to the Company's April 2006 S-3
10.14	Amended and Restated License Agreement dated February 23, 2006 by and between OrthoLogic Corp. and Arizona Science Technology Enterprises, LLC	Exhibit 10.5 to the Company's Registration Statement on Form S-3 filed with the SEC on April 25, 2006
10.15	2005 Equity Incentive Plan (2005 Plan) (1)	Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 18, 2006
10.16	Form of Incentive Stock Option Grant Letters for Grants under the 2005 Plan (***)	Exhibit 10.1 to the Company's Report on Form 10-Q for the quarterly period ended June 30, 2006, filed on August 8, 2006 ("June 2006 10-Q")
10.17	Form of Non-Qualified Stock Options Grant Letter for Grants under the 2005 Plan (***)	Exhibit 10.2 to the Company's June 2006 10-Q
10.18	Form of Restricted Stock Grant Letters for Grants under the 2005 Plan (***)	Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on May 18, 2006
10.19	Amendment to Employment Agreement dated January 10, 2006 between OrthoLogic Corp. and Les Taeger (1)	Exhibit 10.3 to the Company's June 2006 10-Q
10.20	Employment Agreement between Randolph C. Steer, MD, Ph.D., President, and OrthoLogic Corp., effective May 12, 2006 (1)	Exhibit 10.7 to the Company's June 2006 10-Q
10.21	Management Service Agreement between Valley Ventures III, Management LLC, John M. Holliman, III, Executive Chairman and OrthoLogic Corp., effective May 12, 2006 (1)	Exhibit 10.8 to the Company's June 2006 10-Q
10.22	Amendment No.1 to Registration Rights Agreement dated June 30, 2006 by and between PharmaBio Development Inc., and OrthoLogic Corp.	Exhibit 4.9 to the Company's Amendment No. 1 to Registration Statement on Form 8-A/A , filed with the SEC on May 25, 2010.
10.23	Lease Agreement dated July 19, 2007, by and between the Company and Phoenix Investors #13, L.L.C.	Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 23, 2007

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|-------|---|---|
| 10.24 | Amendment #1 to Employment Agreement dated May 21, 2007, between Randolph C. Steer, MD, Ph.D., President, and OrthoLogic Corp.  | Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2007, filed with the SEC on March 5, 2008.  |
| 10.25 | Amendment #2 to Employment Agreement dated February 21, 2008, between Randolph C. Steer, MD, Ph.D., President, and OrthoLogic Corp.   | Exhibit 10.31 to the Company's Annual Report on Form 10-K for the year ended December 31, 2007, filed with the SEC on March 5, 2008.  |
| 10.26 | Amendment No. 3, dated November 4, 2008, to the Management Services Agreement effective May 12, 2006 by and between AGP Management, LP, John M. Holliman, III, Executive Chairman, and OrthoLogic Corp. (1) | Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2008, filed with the SEC on November 6, 2008 (the "November 6, 2008 10-Q") |
| 10.27 | Amendment No. 3, dated November 4, 2008, to the Employment Agreement effective May 12, 2006, between Randolph C. Steer, MD, Ph.D., President, and OrthoLogic Corp. (1)                                      | Exhibit 10.2 to the Company's November 6, 2008 10-Q   |

10.28	First Amendment to Lease dated April 28, 2010 by and between OrthoLogic Corp. and Phoenix Investors #20, L.L.C.	Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2010, filed with the SEC on August 9, 2010	
23.1	Consent of independent registered public accounting firm.		X
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a -14(a) of the Securities Exchange Act of 1934, as amended		X
31.2	Certification of Principal Financial and Accounting Officer Pursuant to Rule 13a - 14(a) of the Securities Exchange Act of 1934, as amended		X
32.1	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350****		

(1) Management contract or compensatory plan or arrangement.

(2) Portions of this agreement have been redacted and filed under confidential treatment request with the Securities and Exchange Commission.

\* Upon the request of the Securities and Exchange Commission, Capstone Therapeutics Corp. agrees to furnish supplementally a copy of any schedule to the Asset Purchase Agreement and Plan of Reorganization between the Company and Chrysalis Biotechnology, Inc., dated as of April 28, 2004, as amended and the Asset Purchase Agreement and Plan of Reorganization by and between the Company and AzERx, Inc., dated February 23, 2006.

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

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

\*\*\*\* Furnished herewith.

FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Capstone Therapeutics Corp.

We have audited the accompanying balance sheets of Capstone Therapeutics Corp. (formerly OrthoLogic Corp.) (a development stage company) (the Company) as of December 31, 2010 and 2009, and the related statements of operations, potentially redeemable equity and stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2010, and for the period August 5, 2004 (inception) through December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting.

Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Capstone Therapeutics Corp. (a development stage company) as of December 31, 2010 and 2009 and the results of its operations and its cash flows for each of the two years ended December 31, 2009 and the period from August 5, 2004 (inception) through December 31, 2010, in conformity with United States generally accepted accounting principles.

As discussed in Note 1 to the financial statements, the uncertainty with regards to the exercise of the put rights raises substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might results from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Phoenix, Arizona  
March 29, 2011

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CAPSTONE THERAPEUTICS CORP.  
 (Formerly OrthoLogic Corp.)  
 (A Development Stage Company)  
 BALANCE SHEETS  
 (in thousands, except share and per share data)

	December 31, 2010	December 31, 2009
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 24,387	\$ 12,874
Short-term investments	-	22,268
Interest, income taxes and other current assets	643	1,660
Total current assets	25,030	36,802
Furniture and equipment, net	258	333
Total assets	\$ 25,288	\$ 37,135
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 246	\$ 719
Accrued compensation	674	549
Accrued clinical and other accrued liabilities	236	1,139
Share-based payments liability	660	-
Total current liabilities	1,816	2,407
Potentially redeemable equity - See Note 10	15,556	-
Stockholders' Equity		
Common Stock \$.0005 par value; 100,000,000 shares authorized; 40,775,411 shares in 2010 and 2009 issued and outstanding	20	20
Additional paid-in capital	188,258	188,643
Accumulated deficit (\$152,600 at 2010 and \$126,173 at 2009) accumulated during development stage period)	(180,362 )	(153,935 )
Total stockholders' equity	7,916	34,728
Total liabilities, potentially redeemable equity and stockholders' equity	\$ 25,288	\$ 37,135

See notes to financial statements

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

	Years ended December 31,		As a Development Stage Company August 5, 2004 - December 31, 2010
	2010	2009	
<b>OPERATING EXPENSES</b>			
General and administrative	\$ 3,240	\$ 2,901	\$ 26,216
Research and development	8,168	11,968	93,655
Purchased in-process research and development	-	-	34,311
Other	-	-	(375 )
Total operating expenses	11,408	14,869	153,807
Interest and other income, net	(356 )	(737 )	(13,727 )
Loss from continuing operations before taxes	11,052	14,132	140,080
Income tax benefit	(181 )	(1,009 )	(1,197 )
Loss from continuing operations	10,871	13,123	138,883
<b>Discontinued Operations -</b>			
net gain on the sale of the bone device business, net of taxes of \$267	-	-	(2,202 )
<b>NET LOSS</b>	<b>\$ 10,871</b>	<b>\$ 13,123</b>	<b>\$ 136,681</b>
<b>Per Share Information:</b>			
Net loss, basic and diluted	\$ 0.27	\$ 0.32	
Basic and diluted shares outstanding	40,775	40,775	

See notes to financial statements

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Capstone Therapeutics  
(Formerly OrthoLogic Corp.)  
(A Development Stage Company)  
STATEMENTS OF POTENTIALLY REDEEMABLE EQUITY AND  
STOCKHOLDERS' EQUITY  
(in thousands)

	Potentially Redeemable	Common Stock		Stockholders' Equity		Total
	Equity	Shares	Amount	Additional Paid in Capital	Accumulated Deficit	
Balance August 5, 2004 (prior to the acquisition of CBI)	\$ -	34,550	\$ 17	\$ 146,125	\$ (27,762 )	\$ 118,380
Acquisition of CBI, August 5, 2004	-	3,248	2	23,451	-	23,453
Acquisition of AzERx, February 27, 2006	-	1,355	1	7,763	-	7,764
Exercise of common stock options	-	997	-	4,579	-	4,579
Stock-based compensation cost	-	-	-	2,861	-	2,861
Compensation earned on stock awards	-	494	-	1,200	-	1,200
Sale of common stock	-	1,263	1	3,375	-	3,376
Common stock purchased and retired	-	(1,132 )	(1 )	(1,040 )	-	(1,041 )
Recognized uncertain tax position	-	-	-	-	(363 )	(363 )
Net loss August 5, 2004 through December 31, 2008	-	-	-	-	(112,687)	(112,687)
Balance December 31, 2008	-	40,775	20	188,314	(140,812)	47,522
Stock-based compensation cost	-	-	-	329	-	329
Net loss	-	-	-	-	(13,123 )	(13,123 )
Balance December 31, 2009	-	40,775	20	188,643	(153,935)	34,728
Recognition of potentially redeemable equity, net of amortization	15,556	-	-	-	(15,556 )	(15,556 )
Stock-based compensation cost	-	-	-	156	-	156
Reclassification of share-based awards liability	-	-	-	(541 )	-	(541 )
Net loss	-	-	-	-	(10,871 )	(10,871 )
Balance December 31, 2010	\$ 15,556	40,775	\$ 20	\$ 188,258	\$ (180,362)	\$ 7,916

See notes to financial statements



CAPSTONE THERAPEUTICS CORP.  
(Formerly OrthoLogic Corp.)  
(A Development Stage Company)  
STATEMENTS OF CASH FLOWS  
(in thousands)

	Years Ended December 31,		As a Development Stage Company August 5, 2004 - December 31, 2010
	2010	2009	
<b>OPERATING ACTIVITIES</b>			
Net loss	\$ (10,871 )	\$ (13,123 )	\$ (136,681 )
Non cash items:			
Deferred tax expense	-	-	770
Depreciation and amortization	135	125	3,825
Non-cash stock-based compensation	275	329	4,665
Gain on sale of bone device business	-	-	(2,298 )
In-process research and development	-	-	34,311
Change in other operating items:			
Interest, income taxes and other current assets	1,017	(566 )	1,065
Accounts payable	(473 )	(344 )	(725 )
Accrued liabilities	(778 )	759	(2,104 )
Cash flows used in operating activities	(10,695 )	(12,820 )	(97,172 )
<b>INVESTING ACTIVITIES</b>			
Expenditures for furniture and equipment, net	(60 )	(22 )	(1,025 )
Proceeds from sale of assets	-	-	7,000
Cash paid for assets of AzERx/CBI	-	-	(4,058 )
Cash paid for patent assignment rights	-	-	(650 )
Purchases of investments	(25,140 )	(30,352 )	(282,538 )
Maturities of investments	47,408	32,980	340,476
Cash flows provided by investing activities	22,208	2,606	59,205
<b>FINANCING ACTIVITIES</b>			
Net proceeds from stock option exercises	-	-	4,612
Net proceeds from sale of stock	-	-	3,376
Common stock purchases	-	-	(1,041 )
Cash flows provided by financing activities	-	-	6,947
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>11,513</b>	<b>(10,214 )</b>	<b>(31,020 )</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>12,874</b>	<b>23,088</b>	<b>55,407</b>
<b>CASH AND CASH EQUIVALENTS, END OF YEAR</b>	<b>\$ 24,387</b>	<b>\$ 12,874</b>	<b>\$ 24,387</b>
<b>Supplemental Disclosure of Non-Cash Investing Activities</b>			
<b>AzERx / CBI Acquisitions</b>			
Current assets acquired	\$ -	\$ -	\$ 29
Patents acquired	-	-	2,142

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Liabilities acquired, and accrued acquisition costs	-	-	(457 )
Original investment reversal	-	-	(750 )
In-process research and development acquired	-	-	34,311
Common stock issued for acquisitions	-	-	(31,217 )
Cash paid for acquisitions	\$ -	\$ -	\$ 4,058

See notes to financial statements

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CAPSTONE THERAPEUTICS CORP.

(Formerly OrthoLogic Corp.)

(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

1.SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of the business

Capstone is a biotechnology company committed to developing a pipeline of novel peptides and other molecules aimed at helping patients with under-served conditions. We are focused on the development and commercialization of two product platforms: AZX100 and Chrysalin (TP508).

AZX100 is a novel synthetic 24-amino acid peptide and is believed to have smooth muscle relaxation and anti-fibrotic properties. AZX100 is currently being evaluated for medically and commercially significant applications, such as prevention of hypertrophic and keloid scarring, treatment of pulmonary disease and vascular intimal hyperplasia. We filed an IND for a dermal scarring indication in 2007 and completed Phase 1a and Phase 1b safety clinical trials in dermal scarring in 2008. We commenced Phase 2 clinical trials in dermal scarring following shoulder surgery and keloid scar revision in the first quarter of 2009. During 2010 we completed and reported results for our clinical trials in keloid scar revision and substantially completed our Phase 2 clinical trial in dermal scarring following shoulder surgery. We have an exclusive worldwide license to AZX100.

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 have primarily investigated Chrysalin in two indications, fracture repair and diabetic foot ulcer healing and our efforts are currently focused on development partnering or licensing opportunities for Chrysalin. We own certain worldwide rights to Chrysalin.

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 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, 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.

Our development activities for AZX100 and Chrysalin 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. Through December 31, 2010, we have incurred \$137 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 these notes, references to “we”, “our”, the “Company”, “Capstone Therapeutics”, “Capstone”, and “OrthoLogic” refer to Capstone Therapeutics Corp. References to our Bone Device Business refer to our former business line of bone growth stimulation and fracture fixation devices, including the OL1000 product line, SpinaLogic®, OrthoFrame® and OrthoFrame/Mayo.

**Basis of presentation.** The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As further discussed in Note 10, the exercise of all, or a substantial amount, of the put rights could result in the utilization of a significant amount of the Company’s financial resources and/or result in a liquidation of the Company. The resolution of this uncertainty may not be known by management before June 30, 2011 and these financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

The significant estimates include the Chrysalis Biotechnology, Inc. and AzERx purchase price allocations, income taxes, contingencies, accounting for stock-based compensation and valuation of the put rights and potentially redeemable equity.

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

**Cash and cash equivalents.** Cash and cash equivalents consist of cash on hand and cash deposited with financial institutions, including money market accounts, and investments purchased with a remaining maturity of three months or less when acquired.

**Furniture and equipment.** Furniture and equipment are stated at cost. Depreciation is calculated on a straight-line basis over the estimated useful lives of the various assets, which range





from three to seven years. Leasehold improvements are amortized over the life of the asset or the period of the respective lease using the straight-line method, whichever is the shortest.

Patents. Patent costs related to the acquisition of CBI and rights associated with Chrysalin were being amortized over the estimated life of the patents, 6 - 17 years. On November 2, 2006, the Company announced that it has no immediate plans to re-enter clinical trials for Chrysalin-based product candidates and a strategic shift in its development approach for Chrysalin. The Company currently intends to pursue development partnering or licensing opportunities for its Chrysalin-based product candidates, a change from its previous development history of independently conducting human clinical trials necessary to advance its Chrysalin-based product candidates to market. Financial Accounting Standards Board Accounting Standard Codification (“ASC”) Topic 350.30.35 “General Intangibles other than Goodwill, Subsequent Measurement” requires an impairment loss be recognized for an amortizable intangible asset whenever the net cash in-flow to be generated from an asset is less than its carrying cost. The Company was unable to determine the timing or amount of net cash in-flow to be generated from Chrysalin-based product candidates. Accordingly, due to this uncertainty, the Company recognized an impairment loss for the amount of unamortized Chrysalin patent costs of \$2,100,000 in 2006.

Research and development expenses. Research and development represents both costs incurred internally for research and development activities, as well as costs incurred to fund the research activities with which we have contracted and certain payments regarding the continued clinical testing of Chrysalin and AZX100. Research and development costs are generally expensed when incurred. Nonrefundable advance payments are capitalized and recorded as expense when the respective product or service is delivered.

Accrued Clinical. Accrued clinical represents the liability recorded on a per subject basis of the costs incurred for our human clinical trials. Total patient costs are based on the specified clinical trial protocol, recognized over the period of time service is provided to the subject. We had no active clinical trials at December 31, 2008. Our Phase 1a and Phase 1b clinical trials for AZX100 in dermal scarring were both commenced and completed during 2008. In the first quarter of 2009, we commenced Phase 2 clinical trials for AZX100 in keloid scar revision and dermal scarring following shoulder surgery. In 2010, we completed our Phase 2 clinical trials in keloid scar revision and substantially completed our Phase 2 clinical trial in dermal scarring following shoulder surgery. At December 31, 2010 and 2009, accounts payable and accrued clinical and other accrued liabilities include \$138,000 and \$1,078,000, respectively, related to the Phase 2 clinical trials.

Stock-based compensation. At December 31, 2005, we had two stock-based employee compensation plans described more fully in Note 5. Prior to January 1, 2006, we accounted for those plans under the recognition and measurement principles of Accounting Principles Board (“APB”) Opinion No. 25, “Accounting for Stock Issued to Employees,” and related interpretations. Stock-based employee compensation cost was normally not recognized, as all options granted under our stock plans had an exercise price equal to the market value of the underlying common stock on the date of grant. Effective January 1, 2006, we adopted SFAS No. 123 (revised 2004), “Share-Based Payment”, now ASC Topic 718 “Compensation - Stock Compensation” (“ASC 718”). ASC 718 requires all share-based payments, including grants of stock options, restricted stock units and employee stock purchase rights, to be recognized in our financial statements based on their respective grant date fair values. Under this standard, the fair value of each grant is estimated on the date of grant using a valuation model that meets certain requirements. Until May 21, 2010 (as further discussed below) we used the Black-Scholes option pricing model to estimate the fair value of our share-based payment awards. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model was affected by our stock price and a number of assumptions, including expected volatility, expected term, risk-free interest rate and an expected dividend yield. We used our historical volatility as adjusted for future expectations. The expected life of the stock options was based on

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historical data and future expectations of when the awards will be exercised. The risk-free interest rate assumption was based on observed interest rates with durations consistent with the expected terms of our stock options. The dividend yield assumption was based on our history and expectation of dividend payouts. The fair value of our restricted stock units was based on the fair market value of our common stock on the date of grant. We evaluated the assumptions used to value our share-based payment awards on a quarterly basis. For non-employees, expense was recognized as the service was provided and when performance was complete in accordance with ASC Topic 505 – 550 “Equity-Based Payments to Non-Employees.”

Stock-based compensation expense recognized in our financial statements in 2006 through May 21, 2010 was based on awards that were ultimately expected to vest. We recognized compensation cost for an award with only service conditions that had a graded vesting schedule on a straight line basis over the requisite service period as if the award was, in-substance, a multiple award. However, the amount of compensation cost recognized at any date was at least equal to the portion of grant-date fair value of the award that was vested at that date. The amount of stock-based compensation expense in 2006 through May 21, 2010 was reduced for estimated forfeitures. Forfeitures were required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates.

Concurrent with the issuance of the put rights (as discussed further at Note 10), all of the Company’s vested and outstanding share-based payments awards were required to be accounted for as liability awards. ASC 718 requires liability classified share-based payments, including grants of stock options, restricted stock units and employee stock purchase rights, to be recorded at fair value as of the grant date and re-measured at each reporting period with subsequent changes charged to operations. At December 31, 2010, the fair value of liability classified stock option awards is calculated utilizing the Black-Scholes option pricing model as probability weighted for potential put right outcomes. The valuation model utilizes inputs including expected volatility, expected life, risk-free interest rate, expected dividends and probability weighting (Level 3 inputs). We use the historical volatility adjusted for future expectations. The expected life is based on the remaining contractual life of the awards. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of our awards. The dividend yield assumption is based on our history and expectation of dividend payouts. The probability-weighting is based on expectations as to the outcome of the exercise of the put rights. The fair value of restricted stock awards classified as liabilities are calculated using the then estimated put price determined as defined in our Certificate of Incorporation. To the extent that we grant additional equity securities to employees, our stock-based compensation expense will be increased by the additional compensation resulting from those additional grants, but will continue to be recorded as a liability and re-measured at each reporting period. Upon settlement, termination or expiration of the put rights, the remaining share-based payment awards liability will be reclassified to stockholders’ equity.

During the year ended December 31, 2010, the Level 3 activity related to the Company’s liability classified share-based payment awards was not material.

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

The Company recorded stock-based compensation of \$275,000 in 2010 and \$329,000 in 2009, which increased the net loss. Loss per weighted average basic and diluted shares outstanding increased by \$0.01 per share in 2010 and \$0.01 per share in 2009 due to stock-based compensation.



Loss per common share. In determining loss per common share for a period, we use weighted average shares outstanding during the period for primary shares and we utilize the treasury stock method to calculate the weighted average shares outstanding during the period for diluted shares. Utilizing the treasury stock method for the year ended December 31, 2010, 206,254 shares were determined to be outstanding, but were excluded from the calculations of diluted loss per share as they were anti-dilutive. At December 31, 2010, options and warrants to purchase 3,774,302 shares of our common stock, at exercise prices ranging from \$0.42 to \$7.83 per share, were outstanding.

Income Taxes. Under ASC Topic 740 “Income Taxes” (“ASC 740”), income taxes are recorded based on current year amounts payable or refundable, as well as the consequences of events that give rise to deferred tax assets and liabilities. We base our estimate of current and deferred taxes on the tax laws and rates that are estimated to be in effect in the periods in which deferred tax liabilities or assets are expected to be settled or realized. Pursuant to ASC 740, we have determined that the deferred tax assets at December 31, 2010 require a full valuation allowance given that it is not “more-likely-than-not” that the assets will be recovered.

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

Based on our evaluation upon the adoption of ASC 740 on January 1, 2007 and in accordance with ASC 740, the Company recognized a cumulative-effect adjustment of \$363,000 at January 1, 2007, increasing its liability for unrecognized tax benefits, interest, and penalties and increasing accumulated deficit. Subsequent to adoption of ASC 740, each period we evaluate the tax years that remain open for assessment for federal and state tax purposes. At December 31, 2010, tax years 2006 through 2010 remain open.

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

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2010	2009
Balance at January 1	\$ -	\$ 638,000
Additions based on tax positions related to the current year	-	-
Additions for tax positions of prior years	-	-
Reductions for tax positions of prior years	-	-
Settlements	-	-
Reductions due to lapse in statute of limitations	-	(638,000)
Balance at December 31	\$ -	\$ -

Included in the gross amount of unrecognized tax benefits, as of December 31, 2008, were \$638,000 of unrecognized tax benefits that would not impact the Company’s effective tax rate as we had a full valuation allowance at December 31, 2008.



We may, from time-to-time, be assessed interest or penalties by major tax jurisdictions, although any such assessments historically have been minimal and immaterial to our financial results. The Company recognizes accrued interest and penalties, if applicable, related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2010 and 2009, the Company did not recognize a material amount in interest and penalties.

Put rights: The put rights are considered embedded equity derivatives within our common stock under derivatives accounting standards. The fair value of the put rights has been bifurcated from the value of our potentially redeemable equity and we recognized subsequent changes in the fair value of the put rights within the statement of operations. At December 31, 2010, the value of the bifurcated put right liability was not material.

## 2. INVESTMENTS

At December 31, 2010 and December 31, 2009, investments were classified as held-to-maturity securities, as we do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. Such classification requires these securities to be reported at amortized cost unless they are deemed to be permanently or other-than-temporarily impaired in value.

As of December 31, 2010, all investments were converted into investments with maturities less than 90 days and are included in cash and cash equivalents.

A summary of the fair market value and unrealized gains and losses on these securities at December 31, 2009 is as follows (in thousands):

	Amortized cost	Gross unrealized Gain	Gross unrealized Loss	Fair value
Short-term investments				
US Government Securities	\$ 2,220	\$ 10	\$ -	\$ 2,230
Government-Sponsored Enterprise Securities	1,104	-	(23 )	1,081
Corporate Debt Securities	18,944	2	(230 )	18,716
Total short-term investments	\$ 22,268	\$ 12	\$ (253 )	\$ 22,027

## 3. FURNITURE AND EQUIPMENT

	December 31,	
	2010	2009
Machinery and equipment	\$1,196	\$1,136
Furniture and fixtures	69	69
Leasehold improvements	36	36
	1,301	1,241
Less accumulated depreciation and amortization	(1,043 )	(908 )
Total	\$258	\$333

Depreciation and leasehold improvement amortization expenses for the years ended December 31, 2010 and 2009, and for the period of August 5, 2004 through December 31, 2010 were \$135,000, \$125,000 and \$1,199,000, respectively.





## 4. INCOME TAXES

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

	December 31,	
	2010	2009
Accruals and reserves	\$78	\$78
Valuation allowance	(78 )	(78 )
Total current	-	-
NOL, AMT and general business credit carryforwards	50,698	47,309
Difference in basis of fixed assets	81	72
Accruals and reserves	888	854
Difference in basis of intangibles	460	484
Valuation allowance	(52,127 )	(48,719 )
Total non current	-	-
Total deferred income taxes	\$-	\$-

ASC 740 requires that a valuation allowance be established when it is more-likely-than-not that all or a portion of a deferred tax asset will not be realized. Changes in valuation allowances from period-to-period are included in the tax provision in the period of change. In determining whether a valuation allowance is required, we take into account all evidence with regard to the utilization of a deferred tax asset including past earnings history, expected future earnings, the character and jurisdiction of such earnings, unsettled circumstances that, if unfavorably resolved, would adversely affect utilization of a deferred tax asset, carryback and carryforward periods, and tax strategies that could potentially enhance the likelihood of realization of a deferred tax asset. Management has evaluated the available evidence about future taxable income and other possible sources of realization of deferred tax assets and has established a valuation allowance of approximately \$52 million and \$49 million at December 31, 2010 and 2009, respectively. The valuation allowance at both 2010 and 2009 includes approximately \$2.7 million for net operating loss carry forwards that relate to stock compensation expense for income tax reporting purposes that upon realization, would be recorded as additional paid-in capital. The valuation allowance reduces deferred tax assets to an amount that management believes will more likely than not be realized.

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

	Years Ended December		As a Development Stage Company
	31		August 5, 2004 - December 31,
	2010	2009	2010
Provision (benefit) for income taxes			
Current	\$ (181 )	\$ (1,009 )	\$ (2,303 )
Deferred	-	-	1,106
Income tax provision (benefit)	\$ (181 )	\$ (1,009 )	\$ (1,197 )

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



research and development tax credits to reduce 2010 their Arizona state income taxes currently payable.

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

We have accumulated approximately \$125 million in federal and \$65 million in state net operating loss carryforwards ("NOLs") and approximately \$5 million of research and development and alternative minimum tax credit carryforwards. The federal NOLs expire between 2023 and 2030. The Arizona state NOL's expire between 2011 and 2015. The availability of these NOL's to offset future taxable income could be limited in the event of a change in ownership, as defined in Section 382 of the Internal Revenue Code.

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

A reconciliation of the difference between the provision (benefit) for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows for the years ended December 31, 2010 and 2009 and for the period of August 5, 2004 through December 31, 2010 (in thousands):

	Years Ended December		As a
	31		Development
	2010	2009	Stage Company
			August 5, 2004 -
			December 31,
	2010	2009	2010
Income tax provision (benefit) at statutory rate	\$ (3,758 )	\$ (4,805 )	\$ (47,625 )
State income taxes	(508 )	(650 )	(5,339 )
Purchased in-process			
research and development	-	-	12,533
Research credits	(408 )	(395 )	(5,581 )
Change in uncertain tax position reserve	-	-	(363 )
Expiration of state NOL	914	1,250	2,164
Other	171	80	1,431
Change in valuation allowance	3,408	3,511	41,583
Net provision (benefit)	\$ (181 )	\$ (1,009 )	\$ (1,197 )

5. STOCKHOLDERS' EQUITY

The number of common shares reserved for issuance under the OrthoLogic 1987 option plan was 4,160,000 shares. This plan expired during October 1997. In May 1997, our stockholders adopted a new stock option plan (the "1997 Plan"). The 1997 Plan reserved for issuance 1,040,000 shares of Common Stock. Subsequent to its original adoption, the Board of Directors and stockholders approved amendments to the 1997 Plan that increased the number of shares of common stock reserved for issuance to 4,190,000. The 1997 Plan expired in March 2007. In May 2006, our stockholders approved the 2005 Equity Incentive Plan (the "2005 Plan") and reserved 2,000,000 shares of our common stock for issuance. In May 2009, our stockholders approved the reservation of an additional 1,250,000 shares of common stock for issuance under the 2005 Plan, which increased the total shares available for grant under the 2005 Plan to 3,250,000 shares. At December 31, 2010, 449,502 shares remained available to grant under the 2005 Plan (the 1997 plan and the 2005 plan are collectively referred to as "The Plans"). Two types of options may be granted under the Plans: options intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code (the "Code") and other options not specifically authorized or qualified for favorable income tax treatment by the Code. All eligible employees may receive more than one type of option. Any director or consultant who is not an employee of the Company shall be eligible to receive only nonqualified stock options under the Plans.

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

#### 2010 Stock Options

On January 1, 2010, the Company granted each director a fully vested option to purchase 10,000 shares of the Company's common stock with the exercise price determined by the closing market price on the date of grant (\$0.72). The options have a ten-year term.

On February 4, 2010, the Company granted options to employees to purchase 324,000 shares of the Company's common stock with the exercise price determined by the closing market price on the date of grant (\$0.82). The options have a ten-year term and vest monthly over a two-year period.

On May 21, 2010, the Company granted two directors fully vested options to purchase shares (Dr. Spiegel 50,000 shares and Dr. Wardell 15,000 shares) of the Company's common stock with the exercise price determined by the closing market price on the date of grant (\$0.82). These options have a ten-year term.

On December 14, 2010, the Company granted options to an employee to purchase 25,000 shares of the Company's common stock with the exercise price determined by the closing market price on the date of grant (\$0.52). The options have a ten-year term and vest monthly over a four year period.

We used the Black-Scholes model with the following assumptions to determine the total fair value of \$168,000 for options to purchase 374,000 shares of our common stock issued during the three months ended March 31, 2010 and the fair value of \$27,000 for options to purchase 65,000 shares of our common stock issued during the three months ended June 30, 2010.



	Three months ended March 31, 2010	Three months ended June 30, 2010
Risk free interest rate	2.3% - 2.7%	2.0%
Volatility	66%	66%
Expected term from vesting	3.9 Years	3.9 Years
Dividend yield	0%	0%

As noted previously, all outstanding share-based payment awards became liability awards on May 21, 2010. The fair value of these liability awards was estimated using the Black-Scholes option pricing model as probability weighted for potential put right outcomes at December 31, 2010. The assumption used to value the liability awards included risk free interest rates of 0%-3.3%, volatility of 70%, expected terms of 1-10 years, a dividend yield of 0% and a probability weighting based on potential put right outcomes.

#### 2009 Stock Options

On October 30, 2008, our Board of Directors conditionally granted each Director an option to purchase 25,000 shares of our common stock, with the exercise price of \$0.70 determined by the closing market price on the date of grant. The options vest ratably over a four-year period.

On January 1, 2009, our Board of Directors conditionally granted each Director fully vested options to purchase 10,000 shares of our common stock, with the exercise price of \$0.42 determined by the closing market price on the date of grant.

On February 3, 2009, our Board of Directors conditionally granted options to employees to purchase 375,000 shares of our common stock, with the exercise price of \$0.45 determined by the closing market price on the date of grant. The options vest ratably over a two-year period.

The options were conditionally granted subject to stockholder approval of Proposal 2 in the Proxy Statement for our Annual Meeting held on May 8, 2009, to amend our 2005 Equity Incentive

Plan (the "Plan") to increase the number of shares available for issuance under the Plan by 1,250,000 shares.

Upon stockholder approval on May 8, 2009 of Proposal 2, the conditional grants became effective. The grants are valued using the closing market price of the Company's common stock on the date of grant. The total fair value of the grants is approximately \$151,000 using the Black-Scholes model based on the following assumptions:

Three months ended June 30, 2009	2.1%
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Risk free interest rate	
Volatility	65%
Expected term from vesting	3.8 years
Dividend yield	0%

#### Summary

Non-cash stock compensation cost for the year ended December 31, 2010, totaled \$275,000. In the Statements of Operations for the year ended December 31, 2010, non-cash stock compensation expense of \$228,000 was recorded as general and administrative expense and \$47,000 was recorded as research and development expense.

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Non-cash stock compensation cost for the year ended December 31, 2009, totaled \$329,000. In the Statements of Operations for the year ended December 31, 2009, non-cash stock compensation expense of \$239,000 was recorded as a general and administrative expense and \$90,000 was recorded as a research and development expense.

No options were exercised in the years ended December 31, 2010 and 2009.

At December 31, 2010, the remaining unamortized non-cash stock compensation costs totaled approximately \$82,000, which will be recognized ratably over the period ending December 31, 2014, with an estimated weighted average period of one year.

A summary of option activity under our stock option plans for the years ended December 31, 2010 and 2009 is as follows:

	2010		2009		
	Number of Options	Weighted average exercise price	Weighted average remaining contractual term (years)	Number of Options	Weighted average exercise price
Options outstanding at the beginning of the year:	3,342,523	\$2.52		2,990,304	\$2.98
Granted	464,000	\$0.79		550,000	\$0.50
Exercised	-			-	
Expired / Forfeited	(196,350 )	\$2.08		(197,781 )	\$3.82
Outstanding at end of year	3,610,173	\$2.32	5.73	3,342,523	\$2.52
Options exercisable at year-end	3,277,541	\$2.48	5.43	2,951,786	\$2.76
Options vested and expected to vest at year end	3,610,173	\$2.32	5.73	3,277,581	\$2.55

The Company had no unvested common stock share awards as of December 31, 2010 and 2009, and no common stock share award activity during the years ended December 31, 2010 and 2009.

It is the Company's policy to issue options from stockholder approved incentive plans. However, if the options are issued as an inducement for an individual to join the Company, the Company may issue stock options outside of stockholder approved plans. The options granted to employees under stockholder approved incentive plans have a ten-year term and vest over a two to four-year period of service. All stock options are granted with an exercise price equal to the current market value on the date of grant and, accordingly, stock options have no intrinsic value on the date of grant. Based on the closing market price of the Company's common stock at December 31, 2010 of \$0.58, stock options exercisable or expected to vest at December 31, 2010, have an intrinsic value of \$58,000.

#### Warrants

At December 31, 2010 and 2009, the Company has fully vested warrants outstanding to purchase 46,706 shares of the Company's common stock with an exercise price of \$6.39 per share which expire in February 2016, and fully vested warrants outstanding to purchase 117,423 shares of the Company's common stock with an exercise price of \$1.91 per share which expire in July 2016. The Company's outstanding warrants are accounted for as liabilities as they are indexed to the Company's common stock, the redemption for which is outside the control of the Company as a result



of the issuance of the put rights. No warrants were exercised during the years ended December 31, 2010 or 2009.

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## 6. COMMITMENTS

During 1998 through 2007, we were obligated under a non-cancelable operating lease agreement for a Tempe, Arizona office and research facility. Rent expense for the years ended December 31, 2010 and 2009, and for the period of August 5, 2004 through December 31, 2010 was \$263,000, \$263,000 and \$4,569,000, respectively. We subleased portions of the Tempe facility to other tenants and approximately 45% of the Tempe facility was subleased through December 2007, which offset our lease expense. The Company recorded \$2,299,000 of sublease income for the period of August 5, 2004 through December 31, 2007. The Company had no sublease income in the years subsequent to 2007.

On July 19, 2007, the Company entered into a new lease, which became effective upon the expiration of its previous lease, for 17,000 square feet of space in the same Tempe, Arizona facility. The new lease calls for monthly rental payments of \$22,000, plus a proportionate share of building operating expenses and property taxes. The term of the new lease is sixty months from March 1, 2008, with an option to extend the lease for an additional twenty-four months with monthly rental payments set at \$24,000, plus a proportionate share of building operating expenses and property taxes, during the extension period. The Company also has the right to terminate the new lease at the end of November 2011 upon payment of an early termination fee of approximately \$158,000. Total base rent for the initial sixty-month term is approximately \$1,316,000, due approximately \$263,000 per year for years 2008 through 2012 and \$44,000 in year 2013.

## 7. 401(K) PLAN

We adopted a 401(k) plan for our employees on July 1, 1993. We may make matching contributions to the plan on behalf of all plan participants, the amount of which is determined by the Board of Directors. We matched approximately \$32,000 in 2010 and \$28,000 in 2009.

## 8. AUTHORIZED PREFERRED STOCK

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

On June 19, 2007, the Company entered into a new Rights Agreement (the "New Rights Agreement") with the Bank of New York. In connection with the New Rights Agreement, we declared a dividend distribution of one Right for each outstanding share of our common stock to stockholders of record as of July 2, 2007 and designated 1,000,000 shares of preferred stock as Series A Preferred Stock. The Right, exercisable upon a Triggering Event as defined in the New Rights Agreement, allows the holder of each share of the Company's common stock to purchase 1/100 of a share of Series A Preferred Stock for \$6.00. (Each 1/100 of a share of Series A Preferred Stock is convertible into \$12 of the Company's common stock). The new rights replace similar rights that the Company issued under its previous Rights Agreement. The New Rights Agreement and the exercise of rights to purchase Series A Preferred Stock pursuant to the terms thereof may delay, defer or prevent a change in control because the terms of any issued Series A Preferred Stock would potentially prohibit our consummation of certain extraordinary corporate transactions without the approval of the Board of Directors. In addition to the anti-takeover effects of the rights granted under the New Rights Agreement, the issuance of preferred stock, generally, could have a dilutive effect on our stockholders.



On May 21, 2010, our Board of Directors approved the First Amendment to the Rights Agreement to extend the expiration date of the Rights Agreement from June 19, 2010 to June 19, 2011.

9. AUTHORIZATION OF COMPANY BUY-BACK OF COMMON STOCK

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

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

10. PUT RIGHTS AND POTENTIALLY REDEEMABLE EQUITY

At our Annual Meeting of Stockholders on May 21, 2010, our stockholders approved an amendment to our Restated Certificate of Incorporation, to provide each record holder of our common stock as of June 30, 2011 with the right to require us, under certain circumstances, to purchase for cash all or a portion of the shares of common stock held by such holder at a formula-based price on or about July 31, 2011 (the "put right"). Unless terminated earlier, the put rights will become exercisable by holders of our common stock as of June 30, 2011. The facilitation of the exercise of the put rights is generally through the use of a tender offer, informing stockholders of the amount of cash that would be paid for each properly exercised put right and the process by which to exercise such put rights. The cash price to be paid to stockholders for each properly exercised put right will be based on a formula calculated by us as of June 30, 2011, which price is intended to approximate the per-share equivalent of 90% of our available cash, defined as the sum of the Company's cash and cash equivalents, liquidation value of the Company's other disposable assets, as determined by the Company's Board of Directors in its sole and absolute discretion, less the amount of funds necessary to satisfy all obligations and liabilities of the Company, including contingent obligations and liabilities, which are then outstanding or would arise if the Company was liquidated, as determined by the Company's Board of Directors in its sole and absolute discretion, as more further described in our Certificate of Incorporation.

The put rights will expire upon the occurrence of certain events, including the entry into a partnering, commercial, investment, or capital raising agreement or any other transaction that our Board of Directors, determines, in its sole and absolute discretion, to be material to the Company, a change in control of the Company, or the approval by the Board of Directors of a plan of liquidation or dissolution. Our obligation to purchase shares pursuant to the put rights is subject to certain conditions, including compliance with all applicable state and federal laws, the availability of sufficient cash to consummate the purchase and the absence of any court or administrative order or proceeding prohibiting or seeking to prohibit consummation of the purchase.

As stated above, the Company's obligation to purchase shares upon exercise of the put rights is subject to various conditions. One condition is that such purchases will not violate applicable law, including Section 160 of the Delaware General Corporation Law (DGCL) relating to share repurchases that may impair capital. Because the pending qui tam litigation described in Note 11 below seeks potentially significant damages that, if awarded, could exceed the financial resources of the Company, the pendency of this claim at the time of share repurchases pursuant to the put rights could cause the share repurchases to violate Section 160 of the DGCL and the Uniform Fraudulent Transfer Act.



In addition, in determining the price per share to be paid to stockholders upon exercise of the put rights, our Board of Directors must value all contingent liabilities, including the qui tam lawsuit. Our Board of Directors may determine that, even if the probability of an unsuccessful outcome of this litigation is low, the magnitude of the potential damages that may be awarded in an unfavorable verdict is such that the value ascribed to this contingent liability would cause the per share purchase price upon exercise of the put rights to be zero or nearly zero.

In light of the foregoing, absent settlement, dismissal or other developments in the qui tam litigation or other changes in circumstance, the Company may not be able to purchase shares upon exercise of the put rights, the per share purchase price to be determined by the Board for the put rights may be zero, or the mechanism for the exercise of the put rights and payment of the put price may be changed.

The put rights are considered a bifurcated, embedded equity derivative instrument. To record the effect of the put rights requires difficult estimates and is very subjective. We measure the estimated fair value of the put rights based on market transactions which consider the impact of a put right feature within an entity's common stock at the time of an event that would negatively affect the price of a company's common stock (Level 3 inputs). The estimated fair value of the put rights also considered the market value of our common stock in relation to the estimated put price at June 30, 2011. We do not believe the fair value of, or the changes in fair value related to, the put rights as of December 31, 2010 are material. The fair value of the put rights is revalued at each reporting period with the change in valuation, if material, reflected in our operating results for that reporting period.

Because the put rights create a potential redemption obligation on June 30, 2011, the estimated amount of that redemption obligation, calculated as of December 31, 2010, has been reclassified from accumulated deficit to potentially redeemable equity to reflect the potential redemption obligation. The estimate of the potential redemption obligation also requires estimates that are very subjective.

There is substantial uncertainty as to if or to what extent, the put rights will be exercised at June 30, 2011. The potential redemption obligation does not currently affect or restrict the funds available for our operations. The potentially redeemable equity is adjusted prospectively for changes in the estimated redemption obligation. Such adjustments will be recorded through accumulated deficit. Because all shareholders participate equally in the put rights, there is no impact on the calculation of earnings per share.

The issuance of the put rights also caused the Company's share-based payment awards to be classified as liability awards and warrants to be accounted for as liabilities. The issuance of the Put Rights did not impact the accounting for the Stockholders' Rights as described in Note 8 to these financial statements, as these Rights continue to be clearly and closely related to the Company's common stock.

## 11. CONTINGENCY – LEGAL PROCEEDINGS

In April 2009, we became aware of a qui tam complaint that was filed under seal by Jeffrey J. Bierman as Relator/Plaintiff on March 28, 2005 in the United States District Court for the District of Massachusetts against 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, the Company, in conjunction with the other defendants, moved to dismiss the amended complaint with prejudice. In response to that motion, Relator/Plaintiff filed a second amended complaint. On August 17, 2010, the Company, in conjunction with the other defendants, moved to dismiss the second amended complaint with prejudice. That motion was denied by the court on December 8, 2010. On January 28, 2011, we, in conjunction with the other defendants, filed our answer to the second amended complaint. The case will now move to the trial process, including discovery proceedings. Based upon the currently available information, we believe that the ultimate resolution of this matter will not have a material effect on our financial position, liquidity or results of operations. However, because of many questions of law and facts that may arise, the outcome of this litigation is uncertain. If we are unable to successfully defer or otherwise dispose of this litigation, and the Relator is awarded the damages sought, the litigation would have a material adverse effect on our financial position, liquidity and results of operations and we would not be able to continue our business as it is presently conducted.

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