

Capstone Therapeutics Corp.  
Form 10-Q  
May 13, 2011

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2011

or

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

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

Commission File Number: 0-21214

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

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

1275 W. Washington Street, Suite 101, 85281  
Tempe, Arizona  
(Address of principal executive offices) (Zip Code)

(602) 286-5520  
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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 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 “smaller reporting company” in Rule 12b-2 of the Exchange Act. Large accelerated filer \_\_\_\_\_ Accelerated filer \_\_\_\_\_ Non-accelerated filer \_\_\_\_\_ (do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

40,775,411 shares of common stock outstanding as of April 30, 2011

CAPSTONE THERAPEUTICS CORP.  
(formerly OrthoLogic Corp.)  
(A Development Stage Company)

INDEX

	Page No.
<u>Forward Looking Statements</u>	<u>3</u>
<b>Part I</b> <u>Financial Information</u>	
<u>Item 1. Financial Statements (Unaudited)</u>	
<u>Condensed Balance Sheets as of March 31, 2011 and December 31, 2010</u>	<u>4</u>
<u>Condensed Statements of Operations for the three months ended March 31, 2011 and 2010</u>	<u>5</u>
<u>Condensed Statements of Cash Flows for three months ended March 31, 2011 and 2010</u>	<u>6</u>
<u>Notes to Condensed Financial Statements</u>	<u>7</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>11</u>
<u>Item 4. Controls and Procedures</u>	<u>13</u>
<b>Part II</b> <u>Other Information</u>	
<u>Item 1. Legal Proceedings</u>	<u>14</u>
<u>Item 1A. Risk Factors</u>	<u>14</u>
<u>Item 6. Exhibits</u>	<u>14</u>

EXHIBIT 10.1  
EXHIBIT 31.1  
EXHIBIT 31.2  
EXHIBIT 32

## Forward Looking Statements

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 Quarterly Report on Form 10-Q should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2010, and 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,” “continue,” or the negative of these terms or other comparable terminology. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond our control and which could materially affect actual results, levels of activity, performance or achievements. Factors that may cause actual results to differ materially from current expectations, which we describe in more detail in our Annual Report for the year ended December 31, 2010, 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 and the ongoing qui tam litigation 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. The forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events and are 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.

## PART I – Financial Information

## Item 1. Financial Statements

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

	March 31, 2011	December 31, 2010
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 21,640	\$ 24,387
Interest, income taxes and other current assets	463	643
Total current assets	22,103	25,030
Furniture and equipment, net	226	258
Total assets	\$ 22,329	\$ 25,288
<b>LIABILITIES, POTENTIALLY REDEEMABLE EQUITY AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 632	\$ 246
Accrued compensation	478	674
Accrued clinical and other accrued liabilities	260	236
Share-based payments liability	375	660
Total current liabilities	1,745	1,816
Potentially redeemable equity - See Note B	-	15,556
Stockholders' Equity		
Common Stock \$.0005 par value; 100,000,000 shares authorized; 40,775,411 shares in 2011 and 2010 issued and outstanding	20	20
Additional paid-in capital	188,607	188,258
Accumulated deficit (\$140,281 at March 31, 2011 and \$152,600 at December 31, 2010, accumulated during development stage period)	(168,043 )	(180,362 )
Total stockholders' equity	20,584	7,916
Total liabilities, potentially redeemable equity and stockholders' equity	\$ 22,329	\$ 25,288

See notes to unaudited condensed financial statements

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

	Three months ended		As a
	March 31,		Development
	2011	2010	Stage
			Company
			August 5,
			2004 -
			March 31,
			2011
<b>OPERATING EXPENSES</b>			
General and administrative	\$ 1,165	\$ 973	\$ 27,381
Research and development	2,082	2,023	95,737
Purchased in-process research and development	-	-	34,311
Other	-	-	(375 )
Total operating expenses	3,247	2,996	157,054
Interest and other income, net	(10 )	(45 )	(13,737 )
Loss from continuing operations before taxes	3,237	2,951	143,317
Income tax benefit	-	-	(1,197 )
Loss from continuing operations	3,237	2,951	142,120
Discontinued operations - net gain on sale of the bone device business, net of taxes of \$267	-	-	(2,202 )
<b>NET LOSS</b>	<b>\$ 3,237</b>	<b>\$ 2,951</b>	<b>\$ 139,918</b>
<b>Per Share Information:</b>			
Net loss, basic and diluted	\$ 0.08	\$ 0.07	
Basic and diluted shares outstanding	40,775	40,775	

See notes to unaudited condensed financial statements

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

	Three months ended		As a Development Stage Company August 5, 2004
	March 31, 2011	March 31, 2010	- March 31, 2011
<b>OPERATING ACTIVITIES</b>			
Net loss	\$ (3,237 )	\$ (2,951 )	\$ (139,918 )
Non cash items:			
Deferred tax expense	-	-	770
Depreciation and amortization	32	33	3,857
Non-cash stock compensation	67	83	4,732
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	180	1,007	1,245
Accounts payable	386	(337 )	(339 )
Accrued liabilities	(175 )	(107 )	(2,279 )
Cash flows used in operating activities	(2,747 )	(2,272 )	(99,919 )
<b>INVESTING ACTIVITIES</b>			
Expenditures for furniture and equipment, net	-	(31 )	(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	-	(12,938 )	(282,538 )
Maturities of investments	-	16,647	340,476
Cash flows provided by investing activities	-	3,678	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 (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>			
	(2,747 )	1,406	(33,767 )
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>			
	24,387	12,874	55,407
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>			
	\$ 21,640	\$ 14,280	\$ 21,640

Supplemental Disclosure of Non-Cash Investing Activities - AzERx/CBI Acquisitions:	AzERx and CBI
Current assets acquired	\$ 29
Patents acquired	2,142
Liabilities acquired, and accrued acquisition costs	(457 )
Original investment reversal	(750 )
In-process research and development acquired	34,311
Common stock issued for acquisition	(31,217 )
Cash paid for acquisition	\$ 4,058

See notes to unaudited condensed financial statements



CAPSTONE THERAPEUTICS CORP.  
(formerly OrthoLogic Corp.)  
(A Development Stage Company)  
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS  
March 31, 2011

## OVERVIEW OF BUSINESS

### 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 March 31, 2011, we have incurred \$140 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.

#### Financial Statement Presentation

In the opinion of management, the unaudited condensed interim financial statements include all adjustments necessary for the fair presentation of our financial position, results of operations, and cash flows, and all adjustments were of a normal recurring nature except for the adjustment related to the grant of shareholders’ put rights as described in Note B to this Quarterly Report on Form 10-Q. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the complete fiscal year.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to Securities and Exchange Commission rules and regulations, although we believe that the disclosures herein are adequate to make the information presented not misleading. These unaudited condensed financial statements should be read in conjunction with the financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2010. Information presented as of December 31, 2010 is derived from audited financial statements.

At December 31, 2010, the uncertainty with regards to the exercise of the put rights (see Note B) raised substantial doubt about the Company’s ability to continue as a going concern. The December 31, 2010 financial statements do not include any adjustments that might have resulted from the outcome of this uncertainty. Based on the disclosures included in this Quarterly Report on Form 10-Q (see Note B) at March 31, 2011, the uncertainty with regards to the exercise of the put rights no longer raises substantial doubt about the Company’s ability to continue as a going concern.

#### Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States 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 us in the future, actual results may differ from these estimates and assumptions.

#### 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 three month period ended March 31, 2011, 57,036 shares of common stock were determined to be outstanding during the period but were excluded from the calculations of diluted loss per share as they were anti-dilutive. At March 31, 2011, options and warrants to purchase 3,848,630 shares of our common stock, at exercise prices ranging from \$0.42 to \$7.83 per share, were outstanding.

#### A. CASH AND CASH EQUIVALENTS

At March 31, 2011 and December 31, 2010, cash and cash equivalents included money market accounts and commercial paper with original maturities of less than 90 days.

#### B. 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 exercise of the put rights would be facilitated 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 distributions to stockholders or share repurchases that may impair capital. Because the pending qui tam litigation described in Note D 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 or distributions to stockholders could cause a violation of 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 has determined that, although it is not probable that there will be an unsuccessful



outcome of this litigation, 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 this calculation would cause the per share purchase price upon exercise of the put rights to be zero.

In light of the foregoing, on April 25, 2011 our Board of Directors decided that, absent settlement, dismissal or other developments in the qui tam litigation or other changes in circumstance by June 30, 2011, the Company will be unable to purchase shares upon exercise of the put rights and therefore, the put rights will expire.

The put rights are considered a bifurcated, embedded equity derivative instrument. We measure the estimated fair value of the put rights based on market transactions that 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 change in fair value related to, the put rights as of March 31, 2011 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 created a potential redemption obligation on June 30, 2011, the estimated amount of that redemption obligation, calculated as of December 31, 2010, was reclassified from accumulated deficit to potentially redeemable equity to reflect the potential redemption obligation. The potentially redeemable equity was amortized, through accumulated deficit, to zero at March 31, 2011 reflecting changes in the estimated redemption obligation. The change in the estimated redemption obligation was based on the decision of the Board of Directors that the Company will be unable to purchase any shares upon exercise of the put rights and therefore, the put rights will expire. Because all shareholders participate equally in the put rights, there is no impact on the calculation of earnings per share.

#### C. SHARE-BASED COMPENSATION

Concurrent with the issuance of the put rights all of the Company's vested and outstanding share-based payments awards were required to be accounted for as liability awards. At March 31, 2011 and December 31, 2010, the fair value of liability classified stock option awards was estimated 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). The assumption used to value the liability awards included risk free interest rates of 0%-3.5%, volatility of 70%, expected terms of 1-10 years, a dividend yield of 0% and a probability weighting based on potential put right outcomes. 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.

During the three months ended March 31, 2011, the Level 3 activity related to the Company's liability classified share-based payment awards resulted in a \$285,000 reduction to the share-based payment liability and an increase to additional paid-in capital.

#### D. 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, the relator served the amended complaint on the Company. We sold our bone growth stimulation business in November 2003 and have had no further activity in the bone growth stimulation business since that date. We intend, in conjunction with the other defendants, to defend this matter vigorously and believe that at all times our billing practices in our bone growth stimulation business complied with applicable laws. On December 4, 2009, the Company, in conjunction with the other defendants, moved to dismiss the amended complaint with prejudice. In response to that motion, relator 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.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following is management's discussion of significant events in the three-month period ended March 31, 2011 and factors that affected our interim financial condition and results of operations. This should be read in conjunction with our "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2010.

### Overview of the Business

Capstone Therapeutics Corp. is a biotechnology company focused on the development and commercialization of the novel synthetic peptides AZX100 and Chrysalin (TP508).

In 2011 and 2010, our activities included:

- Evaluating AZX100 for medically and commercially significant applications, such as prevention or reduction of hypertrophic and keloid scarring and treatment of pulmonary fibrosis. We are executing a development plan for this peptide, which 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. The Studies' Safety Committee reviewing all safety-related aspects of the clinical trials was satisfied with the profile of AZX100. We commenced in the first quarter of 2009 AZX100 Phase 2 human clinical trials in keloid scar revision and dermal scarring following shoulder surgery. These Phase 2 studies completed enrollment in 2009. In 2010 we completed and reported the Phase 2 clinical trials in keloid scar revision. The Phase 2 clinical trial in dermal scarring following shoulder surgery was substantially completed in 2010 and we reported results for this study in April 2011. We continue to perform pre-clinical studies supporting multiple indications for AZX100 and are actively pursuing partnering or collaboration opportunities for the future development of AZX100.

- For Chrysalin, in 2011, we are continuing our vascular partnering/development collaboration efforts. We have no currently planned additional pre-clinical or clinical studies.

#### Critical Accounting Policies

Our critical accounting policies are those that affect, or could affect our financial statements materially and involve a significant level of judgment by management. The accounting policies and related risks described in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 29, 2011, for the year ended December 31, 2010 are those that depend most heavily on these judgments and estimates. As of March 31, 2011, there have been no material changes to any of the critical accounting policies contained in our Annual Report for the year ended December 31, 2010.

#### Results of Operations Comparing Three-Month Period Ended March 31, 2011 to the Corresponding Period in 2010.

**General and Administrative ("G&A") Expenses:** G&A expenses related to our ongoing development operations were \$1,165,000 in the first quarter of 2011 compared to \$973,000 in the first quarter of 2010. Our administrative expenses during the first quarter of 2011 reflect a comparable level of administrative activity as in the same period of 2010 with the increase primarily related to increased investor relations and business development activities.

**Research and Development Expenses:** Research and development expenses were \$2,082,000 for the first quarter of 2011 compared to \$2,023,000 for the first quarter of 2010. Our research and development expenses increased \$59,000 in the first quarter of 2011 compared to the same period in 2010 primarily due to an increase in internal research costs for Mechanism of Action studies and acquisition of peptide (AZX100) with these cost increases substantially offset by reduced clinical costs in 2011 compared to 2010 related to our Phase 2 clinical trials. Our Phase 2 clinical trials for keloid scar revision were completed in 2010 and our Phase 2 clinical trial in dermal scarring following shoulder surgery was substantially completed in 2010.

**Interest and Other Income, Net:** Interest and other income, net decreased from \$45,000 in the first quarter of 2010 to \$10,000 in the first quarter of 2011 due to the reduction in the amount available for investment and the shift in late 2010 to investments with maturities of ninety days or less.

**Net Loss:** We incurred a net loss in the first quarter of 2011 of \$3.2 million compared to a net loss of \$3.0 million in the first quarter of 2010. The \$0.2 million increase in the net loss for the first quarter of 2011 compared to the same period in 2010 resulted primarily from increased investor relations and business development activities and the quarterly comparison was also affected by an increase in internal research costs for Mechanism of Action studies and acquisition of peptide (AZX100) with these cost increases substantially offset by reduced clinical costs in 2011 compared to 2010 related to our Phase 2

clinical trials. Our Phase 2 clinical trials for keloid scar revision were completed in 2010 and our Phase 2 clinical trial in dermal scarring following shoulder surgery was substantially completed in 2010.

#### Liquidity and Capital Resources

Since the sale of our Bone Device Business in November 2003, we have relied on our cash and investments to finance all our operations, the focus of which has been research and development of our Chrysalin and AZX100 product candidates. We received a total of \$100.2 million in cash from the sale of our Bone Device Business. In February 2006, we entered into an agreement with Quintiles (see Note 15 to the financial statements included in 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. We also received net proceeds of \$4,612,000 from the exercise of stock options during our development stage period. At March 31, 2011, we had cash and cash equivalents of \$21.6 million.

We previously 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 intend to continue research and development expenditures for further pre-clinical studies supporting multiple indications for AZX100 and evaluation of the future clinical pathway for AZX100 in dermal scarring.

Our future research and development expenses may vary significantly from prior periods depending on our decisions on 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 cash equivalents at March 31, 2011 will be sufficient to meet our presently projected cash and working capital requirements for the next year. However, to complete the clinical trials and supporting research and production efforts necessary to obtain FDA approval for 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.

#### Item 4. Controls and Procedures

##### 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-Q. 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-Q 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.

#### Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Part II – Other Information

##### Item 1. Legal Proceedings

Reference is made to Item 3. Legal Proceedings in our Form 10-K filed with the Securities and Exchange Commission on March 29, 2011 and to Note D in this Quarterly Report on Form 10-Q, which information is incorporated in this Item 1 by reference.

##### Item 1A. Risk Factors

There are no material changes from the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010.

##### Item 6. Exhibits

See the Exhibit Index following this report.

SIGNATURES

Pursuant to the requirements 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.  
(Registrant)

Signature	Title	Date
/s/ John M. Holliman, III John M. Holliman, III	Executive Chairman (Principal Executive Officer)	May 13, 2011
/s/ Les M. Taeger Les M. Taeger	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	May 13, 2011