

Capstone Therapeutics Corp.  
Form 10-Q  
November 10, 2010

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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 September 30, 2010

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 incorporation or organization) (IRS Employer Identification No.)

1275 W. Washington Street, Suite 101, Tempe, Arizona 85281  
(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” o “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. Large accelerated filer o Accelerated filer o Non-accelerated filer o (do not check if a smaller reporting company) Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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 October 31, 2010

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

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## 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, 2009, 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,” “potential,” “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 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;
- increases or changes in 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 agreements;
- failure to successfully implement our drug development strategy;
- failure in the future to meet the requirements for continued listing on the Nasdaq Capital Market; and
- effect of the 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. 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.

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## 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)

	September 30, 2010 (Unaudited)	December 31, 2009
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 11,693	\$ 12,874
Short-term investments	15,467	22,268
Interest, income taxes and other current assets	419	1,660
Total current assets	27,579	36,802
Furniture and equipment, net	292	333
Total assets	\$ 27,871	\$ 37,135
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 392	\$ 719
Accrued compensation	524	549
Accrued clinical and other accrued liabilities	492	1,139
Total current liabilities	1,408	2,407
Potentially Redeemable Equity - see Note D	15,603	-
Stockholders' Equity		
Common Stock \$.0005 par value; 100,000,000 shares authorized; 40,775,411 shares issued and outstanding in 2010 and 2009	20	20
Additional paid-in capital	188,833	188,643
Accumulated deficit (\$150,231 at September 30, 2010 and \$126,173 at December 31, 2009, accumulated during development stage period)	(177,993 )	(153,935 )
Total stockholders' equity	10,860	34,728
Total liabilities, potentially redeemable equity, and stockholders' equity	\$ 27,871	\$ 37,135

See notes to unaudited condensed financial statements

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## CAPSTONE THERAPEUTICS CORP.

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

	Three months ended September 30,		Nine months ended September 30,		As a Development Stage Company August 5, 2004 - September 30, 2010
	2010	2009	2010	2009	
<b>OPERATING EXPENSES</b>					
General and administrative	\$ 698	\$ 604	\$ 2,460	\$ 2,172	\$ 25,436
Research and development	1,911	2,843	6,094	9,030	91,581
Purchased in-process research and development	-	-	-	-	34,311
Other	-	-	-	-	(375 )
Total operating expenses	2,609	3,447	8,554	11,202	150,953
Interest and other income, net	(28 )	(150 )	(99 )	(641 )	(13,470 )
Loss from continuing operations before taxes	2,581	3,297	8,455	10,561	137,483
Income tax benefit	-	-	-	-	(1,016 )
Loss from continuing operations	2,581	3,297	8,455	10,561	136,467
Discontinued operations - net gain on sale of the bone device business, net of taxes of \$267	-	-	-	-	(2,202 )
NET LOSS	\$ 2,581	\$ 3,297	\$ 8,455	\$ 10,561	\$ 134,265
<b>Per Share Information:</b>					
Net loss, basic and diluted	\$ 0.06	\$ 0.08	\$ 0.21	\$ 0.26	
Basic and diluted shares outstanding	40,775	40,775	40,775	40,775	

See notes to unaudited condensed financial statements

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## CAPSTONE THERAPEUTICS CORP.

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

	Nine months ended September 30,		As a Development Stage Company August 5, 2004 - September 30, 2010
	2010	2009	
<b>OPERATING ACTIVITIES</b>			
Net loss	\$(8,455 )	\$(10,561 )	\$ (134,265 )
Non cash items:			
Deferred tax expense	-	-	770
Depreciation and amortization	101	94	3,791
Non-cash stock compensation	190	261	4,580
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	1,241	464	1,289
Accounts payable	(327 )	(336 )	(579 )
Accrued liabilities	(672 )	793	(1,998 )
Cash flows used in operating activities	(7,922 )	(9,285 )	(94,399 )
<b>INVESTING ACTIVITIES</b>			
Expenditures for furniture and equipment, net	(60 )	(5 )	(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 )	(24,707 )	(282,538 )
Maturities of investments	31,941	25,956	325,009
Cash flows provided by investing activities	6,741	1,244	43,738
<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 IN CASH AND CASH EQUIVALENTS</b>	<b>(1,181 )</b>	<b>(8,041 )</b>	<b>(43,714 )</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 PERIOD</b>	<b>\$11,693</b>	<b>\$15,047</b>	<b>\$ 11,693</b>

Supplemental Disclosure of Non-Cash Investing Activities	AzERx and CBI
AzERx/CBI Acquisitions	

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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



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CAPSTONE THERAPEUTICS CORP.

(formerly OrthoLogic Corp.)

(A Development Stage Company)

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

September 30, 2010

OVERVIEW OF BUSINESS

Description of the Business

Capstone Therapeutics Corp. (formerly OrthoLogic Corp.) 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 that 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 or reduction of hypertrophic and keloid scarring and treatment of pulmonary fibrosis. 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 the remainder of 2010 we expect to 1) complete and report results for our clinical studies in keloid scarring, 2) substantially complete our Phase 2 clinical trial in dermal scarring following shoulder surgery, and 3) perform further pre-clinical studies supporting multiple indications for AZX100. Capstone has an exclusive worldwide license to AZX100.

Chrysalin, 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) modulating inflammatory cytokines; 3) inhibiting apoptosis (programmed cell death); and 4) promoting angiogenesis and revascularization. Chrysalin may have therapeutic value in diseases associated with endothelial dysfunction. We own exclusive worldwide rights to Chrysalin.

We have conducted clinical trials for two potential Chrysalin applications: acceleration of fracture repair and diabetic foot ulcer healing. We previously conducted a pilot clinical trial 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.

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.



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On August 5, 2004, we purchased substantially all of the assets and intellectual property of Chrysalis Biotechnology, Inc. (“CBI”), including exclusive worldwide rights to Chrysalin. 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 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. Through September 30, 2010, we have incurred \$134 million in net losses as a development stage company.

OrthoLogic Corp. commenced doing business under the tradename Capstone Therapeutics on October 1, 2008, and we formally changed our name from OrthoLogic Corp. to Capstone Therapeutics Corp. on May 21, 2010.

In this document, references to “we”, “our”, the “Company”, “Capstone Therapeutics”, “Capstone” and “OrthoLogic Corp.”, 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 D to the September 30, 2010 Condensed Financial Statements included herewith. 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, 2009. Information presented as of December 31, 2009 is derived from audited financial statements.

## 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.

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## Accrued Clinical

Accrued clinical represents the liability recorded on a per patient 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 patient. 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. At September 30, 2010 and December 31, 2009, accounts payable and accrued clinical and other accrued liabilities include \$579,000 and \$1,078,000, respectively, related to the Phase 2 clinical trials.

## 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 and nine month periods ended September 30, 2010, 209,756 and 205,022 shares, respectively, 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 September 30, 2010, options and warrants to purchase 3,759,302 shares of our common stock, at exercise prices ranging from \$0.42 to \$7.83 per share, were outstanding.

## A.Investments and Fair Value Disclosures

At September 30, 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 other than temporarily or permanently impaired in value.

A summary of the fair value (determined by reference to quoted market prices) and unrealized gains and losses on these securities is as follows (in thousands):

	Amortized	Gross Unrealized	Gross Unrealized	Fair Value
September 30, 2010	Cost	Gain	Loss	
Short-Term Investments				
US Government Securities	\$2,767	\$-	\$(8)	\$2,759
Government-Sponsored				
Enterprise Securities	3,150	-	-	3,150
Corporate Debt Securities	9,550	1	(132)	9,419
Total Short-Term Investments	\$15,467	\$1	\$(140)	\$15,328

	Amortized	Gross Unrealized	Gross Unrealized	Fair Value
December 31, 2009	Cost	Gain	Loss	
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

For our cash and cash equivalent investments, the carrying amount is assumed to approximate the fair value because of the liquidity of these instruments.

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## B. Stock Based Compensation

## 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.

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%

## Stock Option Summary

Non-cash stock compensation cost for the nine months ended September 30, 2010 totaled \$190,000. In the Condensed Statements of Operations for the nine months ended September 30, 2010, non-cash stock compensation expense of \$150,000 was recorded as a general and administrative expense and \$40,000 was recorded as a research and development expense.

Non-cash stock compensation cost for the nine months ended September 30, 2009, totaled \$261,000. In the Condensed Statements of Operations for the nine months ended September 30, 2009, non-cash stock compensation expense of \$188,000 was recorded as a general and administrative expense and \$73,000 was recorded as a research and development expense.

No options were exercised in the nine month periods ended September 30, 2010 and 2009.

It is our policy to issue options from shareholder approved incentive plans. However, if the options are issued as an inducement for an individual to join the Company, we may issue stock options outside of shareholder approved plans. Options granted to employees under shareholder approved incentive plans have a ten-year term and vest over a two to four-year period of service. All options and stock purchase rights are granted with an exercise price equal to the closing market price on the date of grant and, accordingly, options or stock purchase rights have no intrinsic value on the date of grant. Based on the closing market price of our common stock at September 30, 2010 of \$0.91, stock options exercisable or expected to vest at September 30, 2010, have an intrinsic value of \$268,000. At September 30, 2010, 474,052 shares remain available to grant under our existing stock plans.

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C. Authorized Preferred Stock

We have 2,000,000 shares of authorized but unissued preferred stock, the terms of which may be fixed by our Board of Directors.

On June 19, 2007, we 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 our 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 our common stock). The new rights replace similar rights that we issued under our 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.

D. Put Rights

At our Annual Meeting of Stockholders on May 21, 2010, our stockholders approved an amendment to our Restated Certificate of Incorporation, which is reflected in Article 5A of the Certificate of Amendment of Restated Certificate of Incorporation filed as Exhibit 3.1 to the Form 8-K filed with the Securities and Exchange Commission on May 25, 2010, 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 attached as Exhibit 3.1 to our current report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2010) as of June 30, 2011.

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 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.



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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. 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 do not believe the fair value of the put rights at September 30, 2010 is material. The fair value of the put rights will be 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 September 30, 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 difficult estimates and is 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 will be adjusted in future periods 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.

Other than the potential put right redemption obligation, the impact of the put rights on other items in the financial statements was determined to be immaterial to the financial position and results of operations of the Company as of and for the three month and nine month periods ended September 30, 2010.

E. 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.

F. Contingency – Legal Proceedings

On or about April 20, 2009, we became aware of a qui tam complaint that was filed under seal by Jeffrey J. Bierman on March 28, 2005 in the United States District Court for the District of Massachusetts against us and other companies that are identified as having 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. Mr. Bierman is seeking civil penalties under various state and federal laws, as well as treble damages.



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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 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 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 moved to dismiss the amended complaint with prejudice. In response to that motion, Realtor/Plaintiff filed a second amended complaint. On August 17, 2010, the Company moved to dismiss the second amended complaint with prejudice. That motion is currently pending. Based upon the currently available information, we believe that the ultimate resolution of this matter will not have a material adverse effect on our financial position, liquidity or results of operations.

## 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 and nine month periods ended September 30, 2010 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" included in our Annual Report on Form 10-K for the year ended December 31, 2009, our "Risk Factors" contained therein and Item 1A. Risk Factors included in Part II of this quarterly report.

### Overview of the Business

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

In 2010 and 2009, 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 will complete and report the Phase 2 clinical trials in keloid scar revision. The Phase 2 clinical trial in dermal scarring following shoulder surgery is targeted to be substantially completed in 2010. We also continued to perform pre-clinical studies supporting multiple indications for AZX100.
- Pre-clinical experiments investigating the potential of Chrysalin to modulate the health of endothelial tissue in blood vessels and other mechanism-of-action studies to support our strategy to partner our vascular product candidates. We did not perform additional pre-clinical or clinical studies in fracture repair, wound healing, spine fusion, cartilage defect repair, dental bone repair or tendon repair. In 2010, we are continuing our vascular partnering/development collaboration efforts.

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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 12, 2010, for the year ended December 31, 2009 and the accounting policies and related risks of the put rights as described in Note D to the Condensed Financial Statements as of and for the three and nine months ended September 30, 2010 included in this current report of Form 10-Q, are those that depend most heavily on these judgments and estimates. As of September 30, 2010, there have been no material changes to any of the critical accounting policies contained in our Annual Report for the year ended December 31, 2009, except for the accounting policies for the put rights.

Results of Operations Comparing Three-Month Period Ended September 30, 2010 to the Corresponding Period in 2009.

**General and Administrative (“G&A”) Expenses:** G&A expenses related to our ongoing development operations were \$698,000 in the third quarter of 2010 compared to \$604,000 in the third quarter of 2009. Our administrative expenses during the third quarter of 2010 reflect a comparable level of administrative activity to the same period of 2009 with the increase primarily related to increased investor relations and business development activities.

**Research and Development Expenses:** Research and development expenses were \$1,911,000 for the third quarter of 2010 compared to \$2,843,000 for the third quarter of 2009. Our research and development expenses decreased \$932,000 in the third quarter of 2010 compared to the same period in 2009 primarily due to reduced clinical costs in 2010 compared to 2009 related to our Phase 2 clinical trials. Costs for our Phase 2 clinical trials were higher in 2009 primarily because costs for study initiation, surgeries and dosing all occurred in 2009, while 2010 costs consisted of monitoring and data gathering and analysis.

**Interest and Other Income, Net:** Interest and other income, net decreased from \$150,000 in the third quarter of 2009 to \$28,000 in the third quarter of 2010 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 third quarter of 2010 of \$2.6 million compared to a net loss of \$3.3 million in the third quarter of 2009. The \$0.7 million decrease in the net loss for the third quarter of 2010 compared to the same period in 2009 resulted primarily from reduced clinical costs in 2010 compared to 2009 related to our Phase 2 clinical trials. Costs for our Phase 2 clinical trials were higher in 2009 primarily because costs for study initiation, surgeries and dosing all occurred in 2009, while 2010 costs consisted of monitoring and data gathering and analysis. These cost decreases were partially 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.

Results of Operations Comparing Nine-Month Period Ended September 30, 2010 to the Corresponding Period in 2009.

**General and Administrative (“G&A”) Expenses:** G&A expenses related to our ongoing development operations were \$2,460,000 in the nine months ended September 30, 2010 compared to \$2,172,000 in the same period in 2009. Our administrative expenses during the nine months ended September 30, 2010 reflect a comparable level of administrative activity to the same period of 2009 with the increase primarily related to increased investor relations, business development and legal expenses in 2010.



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**Research and Development Expenses:** Research and development expenses were \$6,094,000 for the nine months ended September 30, 2010, compared to \$9,030,000 for the same period in 2009. Our research and development expenses decreased \$2,936,000 in the nine months ended September 30, 2010 compared to the same period in 2009 primarily due to a \$600,000 purchase in 2009 of peptide for pre-clinical studies, completion in 2009 of our planned partnering or development collaboration research support activities for Chrysalin, and reduced clinical costs in 2010 compared to 2009 related to our Phase 2 clinical trials. Costs for our Phase 2 clinical trials were higher in 2009 primarily because costs for study initiation, surgeries and dosing all occurred in 2009, while 2010 costs consisted of monitoring and data gathering and analysis. Given the overlapping nature of our research efforts it is not possible to clearly separate research expenditures between AZX100 and Chrysalin; however, the 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 \$641,000 in the nine months ended September 30, 2009 to \$99,000 in the same period in 2010 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 nine months ended September 30, 2010 of \$8.5 million compared to a net loss of \$10.6 million in the same period in 2009. The \$2.1 million decrease in the net loss for the nine months ended September 30, 2010 compared to the same period in 2009 resulted primarily from the purchase in 2009 of peptide for pre-clinical studies, completion in 2009 of our planned partnering or development collaboration research support activities for Chrysalin, and reduced clinical costs in 2010 compared to 2009 related to our Phase 2 clinical trials. Costs for our Phase 2 clinical trials were higher in 2009 primarily because costs for study initiation, surgeries and dosing all occurred in 2009, while 2010 costs consisted of monitoring and data gathering and analysis. These cost decreases were partially 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.

## 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. 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. Since the sale of our Bone Device Business, 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. 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. We also received net proceeds of \$4,612,000 from the exercise of stock options during our development stage period and in January 2010 we received a tax refund of \$1,009,000 for the tax year 2003, related to federal tax legislation enacted in the fourth quarter of 2009. At September 30, 2010, we had cash and cash equivalents of \$11.7 million and short-term investments of \$15.5 million.

We previously announced that we have no immediate plans to re-enter clinical trials for Chrysalin-based product candidates and we have implemented a strategic shift in our development approach for Chrysalin-based product candidates. We currently intend to pursue development partnering, collaboration 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. We will continue research and development expenditures for further pre-clinical studies supporting multiple indications for AZX100 and plan to continue our Phase 2 human clinical trials for dermal scarring following shoulder surgery and keloid scar revision.



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Our future research and development expenses may vary significantly from prior periods depending on our decisions regarding 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 September 30, 2010 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.

To the extent, if at all, the Put Rights are exercised at June 30, 2011, 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 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.



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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 12, 2010.

Item 1A. Risk Factors

Except for the potential effects of our common stock put rights, there are no material changes from the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009. In May 2010, our shareholders approved an amendment to our Restated Certificate of Incorporation which gives shareholders of record on June 30, 2011 a right under certain circumstances to put their shares to us for purchase on or about July 31, 2011. These put rights, and their possible exercise, entail certain risks that shareholders should consider. These risks are discussed under "Proposal 2: Amendment to our Restated Certificate of Incorporation to Provide a 'put right' to Each Holder of our Common Stock as of June 30, 2011 - Risks and Uncertainties Related to the put rights" in our Proxy Statement filed with the SEC on April 12, 2010.

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. We do not currently believe the non-cash effect of the put rights is material to our financial position or results of operations at September 30, 2010, but the put rights are inherently difficult to value. Additionally, Derivative Accounting for the put rights would also affect the accounting for other items in our financial statements but those non-cash effects are not believed to be material to our financial position or results of operations at September 30, 2010; however, these effects are inherently difficult to determine, require difficult estimates and are very subjective.

Item 6. Exhibits

See the Exhibit Index following this report.

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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)	November 10, 2010
/s/ Les M. Taeger Les M. Taeger	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	November 10, 2010

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Capstone Therapeutics Corp.  
(formerly OrthoLogic Corp.)  
(the "Company")

Exhibit Index to Quarterly Report on Form 10-Q  
For the Quarterly Period Ended September 30, 2010

Exhibit No.	Description	Incorporated by Reference To:	Filed Herewith
<u>31.1</u>	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as amended		X
<u>31.2</u>	Certification of Principal Financial and Accounting Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as amended		X
<u>32</u>	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350*		

\* Furnished herewith