

ORTHOLOGIC CORP
Form 10-Q
November 06, 2008

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, 2008

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

ORTHOLOGIC 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 W. Washington Street, Tempe, Arizona
(Address of principal executive offices)

85281
(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 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 Accelerated Non-accelerated Smaller reporting

filer " filer x filer " company "

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

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.

40,731,642 shares of common stock outstanding as of October 31, 2008.

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ORTHOLOGIC CORP.
 (dba Capstone Therapeutics)
 (A Development Stage Company)
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PART I – Financial Information

Item 1.

Financial Statements

ORTHOLOGIC CORP.
 (dba Capstone Therapeutics)
 (A Development Stage Company)
CONDENSED BALANCE SHEETS
 (in thousands, except share and per share data)

	September 30, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current assets		
Cash and cash equivalents	\$ 7,162	\$ 20,943
Short-term investments	39,322	18,236
Prepays and other current assets	1,142	906
Total current assets	47,626	40,085
Furniture and equipment, net		
Long-term investments	366	318
	4,508	21,459
Total assets	\$ 52,500	\$ 61,862
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 905	\$ 702
Accrued compensation	839	824
Other accrued liabilities	629	875
Total current liabilities	2,373	2,401
Stockholders' Equity		
Common Stock \$.0005 par value; 100,000,000 shares authorized; 40,731,642 in 2008 and 41,758,065 in 2007 shares issued and outstanding	20	21
Additional paid-in capital	188,244	189,013
Accumulated deficit	(138,137)	(129,573)
Total stockholders' equity	50,127	59,461
Total liabilities and stockholders' equity	\$ 52,500	\$ 61,862

See notes to unaudited condensed financial statements

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ORTHOLOGIC CORP.
 (dba Capstone Therapeutics)
 (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, 2008
	2008	2007	2008	2007	
OPERATING EXPENSES					
General and administrative	\$ 815	\$ 889	\$ 2,378	\$ 2,797	\$ 19,462
Research and development	2,817	2,369	7,845	7,439	70,671
Purchased in-process research and development	-	-	-	-	34,311
Other	-	-	-	-	(375)
Total operating expenses	3,632	3,258	10,223	10,236	124,069
Interest and other income, net	(488)	(833)	(1,659)	(2,558)	(12,211)
Loss from continuing operations	3,144	2,425	8,564	7,678	111,858
Income tax expense	-	-	-	-	356
Loss from continuing operations	3,144	2,425	8,564	7,678	112,214
Discontinued operations - net gain on sale of the bone device business, net of taxes (\$267)	-	-	-	-	(2,202)
NET LOSS	\$ 3,144	\$ 2,425	\$ 8,564	\$ 7,678	\$ 110,012
Per Share Information:					
Net loss, basic and diluted	\$ 0.08	\$ 0.06	\$ 0.21	\$ 0.18	
Basic and diluted shares outstanding	40,775	41,671	41,200	41,634	

See notes to unaudited condensed financial statements

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ORTHOLOGIC CORP.
 (dba Capstone Therapeutics)
 (A Development Stage Company)
CONDENSED STATEMENTS OF CASH FLOWS
 (in thousands)
 (Unaudited)

	Nine months ended September 30,		As a Development Stage Company August 5th 2004 - September 30, 2008
	2008	2007	
OPERATING ACTIVITIES			
Net loss	\$ (8,564)	\$ (7,678)	\$ (110,012)
Non cash items:			
Deferred tax expense	-	-	770
Depreciation and amortization	99	107	3,533
Non-cash stock compensation	246	591	3,966
Gain on sale of bone device business	-	-	(2,298)
In-process research and development	-	-	34,311
Change in other operating items:			
Prepays and other current assets	(237)	1,048	566
Accounts payable	203	(1,013)	(66)
Accrued liabilities	(229)	(486)	(1,546)
Cash flows used in operating activities	(8,482)	(7,431)	(70,776)
INVESTING ACTIVITIES			
Expenditures for furniture and equipment, net	(148)	(158)	(841)
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	(28,845)	(33,077)	(226,134)
Maturities of investments	24,711	40,802	240,243
Cash flows (used in) provided by investing activities	(4,282)	7,567	15,560
FINANCING ACTIVITIES			
Net proceeds from stock option exercises	-	-	4,612
Net proceeds from sale of stock	-	-	3,376
Common stock purchases	(1,017)	-	(1,017)
Cash flows (used in) provided by financing activities	(1,017)	-	6,971
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS			
	(13,781)	136	(48,245)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	20,943	\$ 18,047	55,407
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 7,162	\$ 18,183	\$ 7,162

	AzERx and CBI
Supplemental Disclosure of Non-Cash Investing Activities	
AzERx/CBI Acquisitions	
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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ORTHOLOGIC CORP.
(dba Capstone Therapeutics)
(A Development Stage Company)
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
September 30, 2008

OVERVIEW OF BUSINESS

Description of the business

On October 1, 2008, OrthoLogic Corp. began doing business under the trade name of Capstone Therapeutics.

OrthoLogic Corp., referred to herein as “OrthoLogic”, “Capstone Therapeutics”, “Capstone”, “the Company”, “we”, “us”, or “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 rusulatide acetate).

AZX100

AZX100, a novel 24-amino acid peptide, 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 a 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 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 treatment of pulmonary disease, prevention of hypertrophic and keloid scarring and intimal hyperplasia. 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. The study’s Safety Committee reviewing all safety-related aspects of the clinical trial was satisfied with the profile of AZX100. On this basis, we initiated a second safety study in dermal scarring (Phase 1b), completion of which is planned for fourth quarter of 2008. Subject to the findings of the Phase 1b study’s Safety Committee, the Company is preparing to initiate Phase 2 human clinical efficacy studies of AZX100 in dermal scarring in the first quarter of 2009. We continue to perform further pre-clinical studies supporting multiple indications 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) upregulating vascular endothelial growth factor; 3) inhibiting apoptosis (programmed cell death); and 4) cytokine modulation resulting in an anti-inflammatory effect. It may have therapeutic value in diseases associated with endothelial dysfunction.

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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. Currently, we are focusing our efforts on pre-clinical studies in vascular applications, such as acute myocardial infarction and chronic myocardial ischemia. If successful, these studies will provide additional support for partnering Chrysalin's future development.

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 company commensurate with the acquisition. Subsequently, all of our collective efforts were focused on research and development of our Chrysalin Product Platform, with the goal of commercializing our products.

On February 27, 2006, the Company purchased certain assets and assumed certain liabilities of AzERx, Inc. Under the terms of the transaction, OrthoLogic acquired an exclusive license for the core intellectual property relating to AZX100.

Our development activities for the Chrysalin Product Platform 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, 2008, we have incurred \$110 million in net losses as a development stage company.

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. 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 the Company believes that the disclosures herein are adequate to make the information presented not misleading. It is suggested that these unaudited condensed financial statements be read in conjunction with the financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007. Information presented as of December 31, 2007 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 of America requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, and expenses in our financial statements and accompanying

notes. Management bases its estimates on historical experience and various other assumptions believed to be reasonable. Although these estimates are based on management's assumptions regarding current events and actions that may impact the Company in the future, actual results may differ from these estimates and assumptions. Our 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 for the year ended December 31, 2007 are those that depend most heavily on these judgments and estimates. As of September 30, 2008, there have been no material changes to any of the critical accounting policies contained therein.

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Adoption of New Accounting Standards

Effective January 1, 2008, the Company adopted the reporting requirements of FASB Statement No. 157 (FAS 157), "Fair Value Measurements", and No. 159, (FAS 159) "Fair Value Option for Financial Assets and Liabilities". FAS 157 establishes a standard framework for measuring fair value in generally accepted accounting principles (GAAP), clarifies the definition of "fair value" within that framework, and expands disclosures about the use of fair value measurements. FAS 159 allows entities to voluntarily choose, at specified election dates, to measure many financial assets and liabilities (as well as certain nonfinancial instruments that are similar to financial instruments) at fair value (the "value option"). The Company did not choose to voluntarily measure any financial assets or liabilities at fair value. The adoption of FAS 157 and FAS 159 did not have an effect on the Company's results of operations or financial position.

A. Stock Based Compensation

2008 Stock Options

On January 1, 2008, the Board of Directors granted each Director a fully vested option to purchase 10,000 shares of the Company's common stock at an exercise price of \$1.35. Additionally, during the three months ended March 31, 2008, the Company granted employees options to purchase 217,173 shares of the Company's common stock at an exercise price of \$1.02. The options vest over a two to four year period.

The Company used the Black-Scholes model with the following assumptions to determine the total fair value of \$147,000 for options to purchase 267,173 shares of the Company's common stock granted during the three months ended March 31, 2008:

	Three months ended March 31, 2008
Risk free interest rate	2.4% - 3.4%
Volatility	57% - 58%
Expected term from vesting	3.7 Years
Dividend yield	0%

2008 Stock Awards

On January 1, 2008, the Board of Directors of the Company awarded 92,595 shares of restricted stock (18,519 shares to each Director), which vest on January 1, 2009. The total fair value of the awards, determined using the closing price of the Company's common stock on the date of grant, was \$125,000, of which \$80,000 has been recognized as compensation cost in the nine months ended September 30, 2008.

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On February 21, 2008, the Company awarded 56,373 fully vested shares of the Company's common stock, having a fair value on the date of the awards of \$57,500, to various employees.

The fair value of the awards was recognized as compensation cost in the three months ended March 31, 2008.

Summary

Non-cash stock compensation cost for the nine months ended September 30, 2008, totaled \$246,000. In the condensed Statements of Operations for the nine months ended September 30, 2008, non-cash stock compensation expense of \$199,000 was recorded as a general and administrative expense and \$47,000 was recorded as a research and development expense.

Non-cash stock compensation cost for the nine months ended September 30, 2007, totaled \$591,000. In the condensed Statements of Operations for the nine months ended September 30, 2007, non-cash stock compensation expense of \$394,000 was recorded as general and administrative expense and \$197,000 was recorded as research and development expense.

No options were exercised in the nine month periods ended September 30, 2008 and 2007.

It is the Company's 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, the Company 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 current market value 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 the Company's common stock at September 30, 2008 of \$0.88, stock options exercisable or expected to vest at September 30, 2008, have no intrinsic value. At September 30, 2008, 26,135 shares remained available to grant under the Company's existing stock option plans.

Warrants

At September 30, 2008, the Company had 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 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.

Additionally (as described in Note 15 to our Annual Report on Form 10-K for the year ended December 31, 2007), performance based warrants to purchase 240,000 shares of the Company's common stock with an exercise price of \$1.91, which expire in February 2016, were outstanding but unvested at September 30, 2008. The total cost of the performance based warrants will be charged to expense over the period of performance. The costs will be determined based on the fair value of the warrants determined by using the Black-Scholes model, revalued at each Company reporting date until fully vested. The fair value of the milestone warrants using the Black-Scholes model, 56% volatility, 0% dividend yield, expected term of 7.4 years, and 3.0% interest rate was \$90,000 at September 30, 2008. No costs were charged to expense at September 30, 2008 as it is not yet probable that any milestone warrants will vest.

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B. Authorization of Company Buy-Back of Common Stock

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

During the nine month period ended September 30, 2008, the Company purchased 1,082,796 shares at a total cost of \$1,017,000.

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 quarter ended September 30, 2008 and factors that affected OrthoLogic's 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, 2007, our "Risk Factors" contained therein and Item 1A. Risk Factors included in Part II of this quarterly report.

Overview of the Business

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

In 2008 and 2007, our efforts were:

- Evaluating AZX100 for medically and commercially significant applications, such as prevention of dermal scarring, pulmonary fibrosis, the treatment of asthma, and vascular intimal hyperplasia. We performed pre-clinical work leading to the filing of an IND for a dermal indication in 2007 and commenced a Phase 1a safety study in dermal scarring in the first quarter of 2008. Our Phase 1a study included 30 subjects and was completed in May 2008. The study's Safety Committee reviewing all safety-related aspects of the clinical trial was satisfied with the profile of AZX100. On this basis, we have initiated a second safety study for dermal scarring (Phase 1b), which included 40 subjects and is planned to be completed in the fourth quarter of 2008. Subject to the findings of the Phase 1b study's Safety Committee, the Company is preparing to initiate Phase 2 human clinical efficacy studies of AZX100 in dermal scarring in the first quarter of 2009. We continue to perform further pre-clinical studies supporting multiple indications for AZX100.
- Pre-clinical experiments examining the potential for Chrysalin in modulating of the health of endothelial tissue in blood vessels. These and other mechanism-of-action studies will support our strategy to partner Chrysalin in vascular applications. 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 2008, we are continuing studies to support our vascular partnering efforts.

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Results of Operations Comparing Three-Month Period Ended September 30, 2008 to the Corresponding Period in 2007.

General and Administrative (“G&A”) Expenses: G&A expenses related to our ongoing development operations decreased by \$74,000 from \$889,000 in the third quarter of 2007 to \$815,000 in the third quarter of 2008. Our G&A expenses during the third quarter of 2008 were lower than the same period of 2007 primarily as a result of general cost containment efforts.

Research and Development Expenses: Research and development expenses were \$2,817,000 for the three months ended September 30, 2008 compared to \$2,369,000 for the three months ended September 30, 2007. Our research and development expenses increased \$448,000 in the second quarter of 2008 compared to the same period in 2007 primarily due to costs incurred for the Phase 1 clinical trials in dermal scarring which commenced in the first quarter of 2008.

Interest and Other Income, Net: Interest and other income, net decreased from \$833,000 in the third quarter of 2007 to \$488,000 in the third quarter of 2008 due to the decrease in interest rates between the two periods and reduction in the amount available for investment.

Net Loss: We incurred a net loss in the three months ended September 30, 2008 of \$3.1 million compared to a net loss of \$2.4 million in the three months ended September 30, 2007. The increase in the net loss for the three months ended September 30, 2008 compared to the same period in 2007, resulted primarily from costs related to our Phase 1 clinical trials in dermal scarring in 2008, and reduced interest income, due to the decrease in interest rates between the two periods and reduction in the amount available for investment.

Results of Operations Comparing Nine-Month Period Ended September 30, 2008 to the Corresponding Period in 2007.

General and Administrative (“G&A”) Expenses: G&A expenses related to our ongoing development operations decreased by \$419,000 from \$2,797,000 in the nine months ended September 30, 2007, to \$2,378,000 in the nine months ended September 30, 2008. Our G&A expenses during the nine months ended September 30, 2008, were lower than the same period of 2007 primarily as a result of general cost containment efforts.

Research and Development Expenses: Research and development expenses were \$7,845,000 for the first nine months in 2008 compared to \$7,439,000 for the first nine months in 2007. Our research and development expenses increased \$406,000 in the nine months ended September 30, 2008, compared to the same period in 2007, primarily due to costs related to our Phase 1 clinical trials in dermal scarring and our previously announced completion of a pre-clinical study to assess the affects of Chrysalin in a model of acute myocardial infarction (heart attack), partially offset by a decline in AZX100 pre-clinical costs related to the filing of an IND in a dermal scarring indication, which was completed as of December 31, 2007. 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 2008 and 2007 are directed towards AZX100 development efforts.

Interest and Other Income, Net: Interest and other income, net decreased from \$2,558,000 in the nine months ended September 30, 2007 to \$1,659,000 in the nine months ended September 30, 2008, due to the decrease in interest rates between the two periods and reduction in the amount available for investment.

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Net Loss: We incurred a net loss in the first nine months of 2008 of \$8.6 million compared to a net loss of \$7.7 million in the first nine months of 2007. The increase in the net loss for the nine months ended September 30, 2008 compared to the same period in 2007, resulted primarily from costs related to our Phase 1 clinical trials in dermal scarring in 2008, and reduced interest income, due to the decrease in interest rates between the two periods and reduction in the amount available for investment, partially offset by lower general and administrative expenses, due to general cost containment efforts, and reduced AZX100 pre-clinical costs related to the filing of an IND for a dermal scarring indication, which was completed as of December 31, 2007.

Liquidity and Capital Resources

We 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. On February 27, 2006, the Company entered into an agreement with Quintiles (see Note 15 in our Annual Report on Form 10-K for the year ended December 31, 2007), which provided an investment by Quintiles in the Company's 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. As of September 30, 2008, we had cash and cash equivalents of \$7.1 million, short-term investments of \$39.3 million and long-term investments of \$4.5 million.