

Ampio Pharmaceuticals, Inc.
Form 10-Q
August 09, 2013
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended: June 30, 2013

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 No. 001-35182

AMPIO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

Delaware
(State or other jurisdiction of
incorporation or organization)

26-0179592
(IRS Employer
Identification No.)

5445 DTC Parkway
Suite 925

Greenwood Village, Colorado 80111

(Address of principal executive offices, including zip code)

(720) 437-6500

(Registrant's telephone number, including area code)

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 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 definition of "accelerated filer", "large accelerated filer" and "smaller reporting company" in Rule 12B-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer
Non-accelerated filer 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

As of August 9, 2013, there were 37,102,426 shares outstanding of Common Stock, par value \$0.0001, of the registrant.

Table of Contents

AMPIO PHARMACEUTICALS, INC.

AND SUBSIDIARIES

SIX MONTHS ENDED JUNE 30, 2013

INDEX

	Page
<u>PART I FINANCIAL INFORMATION</u>	
Item 1. <u>Consolidated Financial Statements</u>	4
<u>Consolidated Balance Sheets as of June 30, 2013 (unaudited) and December 31, 2012</u>	4
<u>Consolidated Statements of Operations for the three and six months ended June 30, 2013 (unaudited), the three and six months ended June 30, 2012 (unaudited), and the period from December 18, 2008 (inception) through June 30, 2013 (unaudited)</u>	5
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	6
<u>Consolidated Statements of Cash Flows for the six months ended June 30, 2013 (unaudited), the six months ended June 30, 2012 (unaudited), and the period from December 18, 2008 (inception) through June 30, 2013 (unaudited)</u>	7
<u>Notes to Consolidated Financial Statements (unaudited)</u>	8
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4. <u>Controls and Procedures</u>	22
<u>PART II OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	23
Item 1A. <u>Risk Factors</u>	23
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
Item 3. <u>Defaults Upon Senior Securities</u>	23
Item 4. <u>Mine Safety Disclosures</u>	23
Item 5. <u>Other Information</u>	23
Item 6. <u>Exhibits</u>	23
<u>SIGNATURES</u>	24

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains statements reflecting assumptions, expectations, projections, intentions or beliefs about future events that are intended as forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this report, other than statements of historical fact, that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. These statements appear in a number of places, including Management's Discussion and Analysis of Financial Condition and Results of Operations. These statements represent our reasonable judgment of the future based on various factors and using numerous assumptions and are subject to known and unknown risks, uncertainties and other factors that could cause our actual results and financial position to differ materially from those contemplated by the statements. You can identify these statements by the fact that they do not relate strictly to historical or current facts, and use words such as anticipate, believe, estimate, expect, forecast, may, should, plan, project and other words of similar meaning. In particular, these include, but are not limited to, statements relating to the following:

projected operating or financial results, including anticipated cash flows used in operations;

expectations regarding capital expenditures, research and development expense and other payments;

our beliefs and assumptions relating to our liquidity position, including our ability to obtain additional financing;

our ability to obtain regulatory approvals for our pharmaceutical drugs and diagnostics; and

our future dependence on third party manufacturers or strategic partners to manufacture any of our pharmaceutical drugs and diagnostics that receive regulatory approval, and our ability to identify strategic partners and enter into license, co-development, collaboration or similar arrangements.

Any or all of our forward-looking statements may turn out to be wrong. They can be affected by inaccurate assumptions or by known or unknown risks, uncertainties and other factors including, among others:

the loss of key management personnel or sponsored research partners on whom we depend;

the progress and results of clinical trials for our product candidates;

our ability to navigate the regulatory approval process in the U.S. and other countries, and our success in obtaining required regulatory approvals for our product candidates;

commercial developments for products that compete with our product candidates;

the actual and perceived effectiveness of our product candidates, and how those product candidates compare to competitive products;

the strength of our intellectual property protection, and our success in avoiding infringing the intellectual property rights of others;

adverse developments in our research and development activities;

potential liability if our product candidates cause illness, injury or death, or adverse publicity from any such events;

our ability to operate our business efficiently, manage capital expenditures and costs (including general and administrative expenses) and obtain financing when required;

our expectations with respect to our acquisition activity.

In addition, there may be other factors that could cause our actual results to be materially different from the results referenced in the forward-looking statements, some of which are included elsewhere in this report, including Management's Discussion and Analysis of Financial Condition and Results of Operations. Many of these factors will be important in determining our actual future results. Consequently, no forward-looking statement can be guaranteed. Our actual future results may vary materially from those expressed or implied in any forward-looking statements. All forward-looking statements contained in this report are qualified in their entirety by this cautionary statement. Forward-looking statements speak only as of the date they are made, and we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of this report, except as otherwise required by applicable law.

This Quarterly Report on Form 10-Q includes trademarks, such as Ampion, Optina, Zertane and Vasaloc, which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. Solely for convenience, our trademarks and tradenames referred to in this Quarterly Report on Form 10-Q may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Consolidated Financial Statements****AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES****(A Development Stage Company)****Consolidated Balance Sheets**

	June 30, 2013 (Unaudited)	December 31, 2012
Assets		
Current assets		
Cash and cash equivalents	\$ 12,456,834	\$ 17,682,517
Prepaid expenses	414,377	164,890
Total current assets	12,871,211	17,847,407
Fixed assets, net		
In-process research and development	315,462	59,290
Patents, net	7,500,000	7,500,000
Deposits	770,351	420,468
	20,000	20,000
	8,605,813	7,999,758
Total assets	\$ 21,477,024	\$ 25,847,165
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	\$ 1,759,034	\$ 1,201,122
Deferred revenue	50,000	50,000
Warrant derivative liability	621,972	384,771
Total current liabilities	2,431,006	1,635,893
Long-term deferred revenue	356,250	381,250
Total liabilities	2,787,256	2,017,143
Commitments and contingencies (Note 6)		
Stockholders equity		
Preferred Stock, par value \$.0001; 10,000,000 shares authorized; none issued		
Common Stock, par value \$.0001; 100,000,000 shares authorized; shares issued and outstanding - 37,095,755 in 2013 and 37,009,695 in 2012	3,709	3,701
Additional paid-in capital	68,691,296	63,687,558
Advances to stockholders	(90,640)	(90,640)

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

Deficit accumulated in the development stage	(50,366,846)	(39,770,597)
Total Ampio stockholders equity	18,237,519	23,830,022
Non-controlling interests	452,249	
Total equity	18,689,768	23,830,022
Total liabilities and equity	\$ 21,477,024	\$ 25,847,165

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES****(A Development Stage Company)****Consolidated Statements of Operations****(unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,		December 18, 2008 (Inception) through June 30, 2013
	2013	2012	2013	2012	
License revenue	\$ 12,500	\$ 12,500	\$ 25,000	\$ 25,000	\$ 93,750
Expenses					
Research and development	\$ 5,249,196	\$ 1,551,629	\$ 8,036,018	\$ 3,024,336	\$ 25,220,743
General and administrative	1,220,346	727,164	2,532,146	2,263,365	16,588,058
Total operating expenses	6,469,542	2,278,793	10,568,164	5,287,701	41,808,801
Other income (expense)					
Interest income	3,172	3,634	7,449	7,187	37,982
Interest expense					(29,317)
Unrealized loss on fair value of debt instruments					(5,547,911)
Derivative expense	(139,389)	(233,226)	(265,867)	(76,247)	(2,983,367)
Total other expense	(136,217)	(229,592)	(258,418)	(69,060)	(8,522,613)
Net loss, before income tax	\$ (6,593,259)	\$ (2,495,885)	\$ (10,801,582)	\$ (5,331,761)	\$ (50,237,664)
Foreign tax expense					82,500
Net loss	\$ (6,593,259)	\$ (2,495,885)	\$ (10,801,582)	\$ (5,331,761)	\$ (50,320,164)
Net loss applicable to non-controlling interests	\$ 175,638	\$	\$ 205,333	\$	\$ 205,333
Net loss applicable to Ampio	\$ (6,417,621)	\$ (2,495,885)	\$ (10,596,249)	\$ (5,331,761)	\$ (50,114,831)
Weighted average number of Ampio common shares outstanding	37,090,989	31,260,070	37,081,800	31,193,378	
Basic and diluted Ampio net loss per common share	\$ (0.17)	\$ (0.08)	\$ (0.29)	\$ (0.17)	

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES****(A Development Stage Company)****Consolidated Statements of Stockholders Equity (Deficit)**

	Series A Preferred Stock		Common Stock		Common Stock	Additional	Additional	Advances	Deficit	Non-	Total
	Shares	Amount	Shares	Amount	Subscribed	Paid in Capital	Issuances	to Stockholders	Accumulated in the Development Stage	controlling Interests	Stockholders Equity (Deficit)
Balance - December 18, 2008 (date of inception)		\$		\$	\$	\$	\$	\$	\$	\$	\$
Issuance of common stock to founder December, 2008			1,080,000	1,080							1,080
Balance - December 31, 2008			1,080,000	1,080							1,080
Issuance of common stock and assumption of liabilities in asset acquisition			3,500,000	3,500					(252,015)		(248,515)
Issuance of Series A Preferred Stock in exchange for cancellation of a note payable in April 2009	163,934	164				199,836					200,000
Issuance of restricted common stock in exchange for cash in April 2009			7,350,000	7,350							7,350
Issuance of Series A Preferred Stock in exchange for cash in April and May 2009	913,930	914				1,114,106					1,115,020
Common stock subscribed in November and December 2009					170,003						170,003
Net loss									(1,512,908)		(1,512,908)
Balance - December 31, 2009	1,077,864	\$ 1,078	11,930,000	\$ 11,930	\$ 170,003	\$ 1,313,942	\$	\$	\$ (1,764,923)	\$	\$ (267,970)

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

Conversion of equity in reverse merger acquisition	(1,077,864)	(1,078)	3,068,958	(10,430)		11,691				183					
Common stock subscribed in March 2010					7,000					7,000					
Issuance of common stock in exchange for cash in March and June 2010, net of offering costs of \$350,000			1,078,078	108	(177,003)	1,536,522				1,359,627					
Issuance of common stock for services			1,030,000	103		1,802,397	(3,281)			1,799,219					
Stock-based compensation						1,297,083				1,297,083					
Loans to shareholders								(150,183)		(150,183)					
Net loss								(8,053,395)		(8,053,395)					
Balance - December 31, 2010	\$		17,107,036	\$	1,711	\$	5,961,635	\$	(3,281)	\$	(150,183)	\$	(9,818,318)	\$	(4,008,436)
Stock-based compensation			13,635		1		1,983,784								1,983,785
Issuance of common stock for services								3,281							3,281
Conversion of debentures			1,281,852		128		9,423,947								9,424,075
Shares issued for cash			1,714				3,000								3,000
Options exercised, net			301,604		30		109,015								109,045
Issuance of common stock for acquisition of DMI BioSciences, Inc., net of 3,500,000 shares of Ampio common stock exchanged			5,167,905		517		7,852,220								7,852,737
Issuance of common stock in exchange for cash in March and April, net of offering costs of \$2,704,328			5,092,880		509		10,916,029								10,916,538
Warrants exercised			88,669		8		784,356								784,364
Shares received in exchange for options issued			(98,416)		(9)		574,009								574,000
Escrow shares claimed			(95,700)		(9)		9								
Repayment of advance									22,660						22,660
Issuance of common stock in exchange for			2,220,255		222		8,453,779								8,454,001

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

cash in December, net of offering costs of \$982,083											
Net loss						(18,359,234)			(18,359,234)		
Balance - December 31, 2011	\$	31,081,434	\$	3,108	\$	46,061,783	\$	(127,523)	\$ (28,177,552)	\$	17,759,816
Issuance of common stock for services		24,072		3		100,147					100,150
Options exercised, net		680,809		68		617,932					618,000
Warrants exercised, net		19,520		2		32,692					32,694
Stock-based compensation						1,522,374					1,522,374
Repayment of advance								36,883			36,883
Issuance of common stock in exchange for cash in July, net of offering costs of \$1,739,589		5,203,860		520		15,352,630					15,353,150
Net loss								(11,593,045)			(11,593,045)
Balance - December 31, 2012	\$	37,009,695	\$	3,701	\$	63,687,558	\$	(90,640)	\$ (39,770,597)	\$	23,830,022
Issuance of common stock for services (unaudited)		22,752		2		88,048					88,050
Issuance of common stock of Luoxis for cash net of offering costs of \$985,274 (Note 2) (unaudited)						3,340,937			639,353		3,980,290
Issuance of common stock of Luoxis in exchange for patents (Note 2) (unaudited)						42,510			7,490		50,000
Non-controlling interests on contributed assets (unaudited)						(10,739)			10,739		
Options exercised, net (unaudited)		54,584		5		128,247					128,252
Warrants exercised, net (unaudited)		8,724		1		43,932					43,933
Stock-based compensation (unaudited)						1,370,803					1,370,803
Net loss (unaudited)								(10,596,249)	(205,333)		(10,801,582)

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

Balance - June 30, 2013 (unaudited)	\$	37,095,755	\$	3,709	\$	68,691,296	\$	(90,640)	\$	(50,366,846)	\$	452,249	\$	18,689,768
---	----	------------	----	-------	----	------------	----	----------	----	--------------	----	---------	----	------------

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES****(A Development Stage Company)****Consolidated Statements of Cash Flows****(unaudited)**

	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012	December 18, 2008 (Inception) through June 30, 2013
Cash flows from operating activities:			
Net loss	\$ (10,801,582)	\$ (5,331,761)	\$ (50,320,164)
Depreciation and amortization	57,759	31,198	162,706
Common stock issued for services	88,050	40,000	1,990,700
Stock-based compensation expense	1,370,803	531,861	6,174,045
Derivative expense	265,867	76,247	2,983,367
Unrealized loss on fair value of debt instruments			5,547,911
Adjustments to reconcile net loss to net cash used in operating activities:			
Increase in prepaid expenses	(249,487)	(262,958)	(414,377)
Increase in related party payable			109,789
Increase (Decrease) in accounts payable	557,912	(272,480)	1,759,036
Increase (Decrease) in deferred revenue	(25,000)	(25,000)	406,250
Increase in accrued interest payable			16,948
Net cash used in operating activities	(8,735,678)	(5,212,893)	(31,583,789)
Cash flows used in investing activities:			
Purchase of fixed assets	(283,814)		(368,519)
Purchase of patents	(330,000)		(330,000)
Deposits			(20,000)
Net cash (used in) investing activities	(613,814)		(718,519)
Cash flows from financing activities:			
Proceeds from related party notes payable and debentures			2,593,000
Proceeds from sale of common stock	143,519	618,000	41,489,943
Costs related to sale of common stock			(4,357,142)
Proceeds from sale of Luoxis common stock (Note 2)	4,652,500		4,652,500
Costs related to sale of Luoxis common stock (Note 2)	(672,210)		(672,210)
Proceeds from common stock subscribed			177,003
Proceeds from sales of Series A Preferred Stock			1,115,020
Advances (to) from shareholders		36,883	(90,640)
Payment of liabilities assumed in asset purchase			(48,515)
Payment of related party notes			(100,000)
Increase in cash from acquisition			183
Net cash provided by financing activities	4,123,809	654,883	44,759,142
Net change in cash and cash equivalents	(5,225,683)	(4,558,010)	12,456,834

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

Cash and cash equivalents at beginning of period	17,682,517	11,362,325	
Cash and cash equivalents at end of period	\$ 12,456,834	\$ 6,804,315	\$ 12,456,834
Supplementary cash flow information:			
Interest paid	\$	\$	\$ 8,358
Income taxes paid	\$	\$	\$ 82,500
Non-cash transactions:			
Liabilities assumed in asset purchase, recorded as a distribution	\$	\$	\$ 248,515
Conversion of notes payable to Series A Preferred Stock	\$	\$	\$ 200,000
Common stock issued for common stock subscriptions received	\$	\$	\$ 177,003
Deferred charge recorded for common stock issued in exchange for services	\$	\$	\$ 1,802,500
Issuance of Luoxis stock for patents (Note 2)	\$ 50,000	\$	\$ 50,000
Common stock issued for acquisition of DMI BioSciences, Inc.	\$	\$	\$ 7,852,737
Conversion of debentures to common stock	\$	\$	\$ 9,424,075
Warrant compensation from common stock offering costs	\$	\$	\$ 1,068,858
Warrant compensation from Luoxis common stock offering costs (Note 2)	\$ 313,064	\$	\$ 313,064
Merger liability - shares exchanged for options	\$	\$	\$ 574,000
Debenture warrant exercise fair value adjustment	\$ 28,666	\$	\$ 678,231

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES****(A Development Stage Company)****Notes to Consolidated Financial Statements****Note 1 Business, Basis of Presentation and Merger**

These unaudited financial statements represent the consolidated financial statements of Ampio Pharmaceuticals, Inc. (Ampio or the Company), formerly known as Chay Enterprises, Inc. (Chay), and its wholly-owned subsidiaries, DMI Life Sciences, Inc. (Life Sciences), DMI Acquisition Corp., DMI BioSciences, Inc. (BioSciences) and Luoxis Diagnostics, Inc. (Luoxis), an 80.9% owned subsidiary see Note 2. These unaudited consolidated financial statements should be read in conjunction with Ampio's annual report on Form 10-K for the year ended December 31, 2012, which included all disclosures required by generally accepted accounting principles. In the opinion of management, these unaudited consolidated financial statements contain all adjustments necessary to present fairly the financial position of Ampio and its results of operations and cash flows for the interim periods presented. The results of operations for the period ended June 30, 2013 are not necessarily indicative of expected operating results for the full year. The information presented throughout the document as of and for the period ended June 30, 2013 is unaudited.

Ampio is a development stage biopharmaceutical company focused on the rapid development of therapies to treat prevalent inflammatory conditions for which there are limited treatment options. We are developing compounds that decrease inflammation by (i) inhibition of specific pro-inflammatory compounds by affecting specific pathways at the protein expression and at the transcription level (ii) activation of a specific phosphatase or depletion of the available phosphate needed for the inflammation process and (iii) decreasing the vascular permeability an upstream event in the inflammation cascade.

Life Sciences was incorporated in the state of Delaware on December 18, 2008 and did not conduct any business activity until April 16, 2009, at which time Life Sciences purchased certain assigned intellectual property (including 107 patents and pending patent applications), business products and tangible property from BioSciences. Life Sciences issued 3,500,000 shares of its common stock to BioSciences, and assumed certain liabilities, as consideration for the assets purchased. The assets that Life Sciences acquired from BioSciences had a carrying value of zero, as BioSciences had expensed all of the research and development costs it incurred with respect to the intellectual property purchased. On March 2, 2010, Life Sciences merged with Chay Acquisitions, a wholly-owned subsidiary of Chay Enterprises, Inc., a public company (the Merger). Chay issued 15,068,942 shares of common stock to acquire Life Sciences, which resulted in the stockholders of Life Sciences owning approximately 95.7% of Chay's outstanding common stock after the consummation of the Merger and before taking into account the issuance of 1,325,000 additional shares of common stock. In conjunction with the Merger, Chay purchased 263,624 shares of its common stock from the Chay Control Shareholders for \$150,000 in cash.

As a result of the Merger, Life Sciences became a wholly owned subsidiary of Chay. For accounting purposes, the Merger was treated as a reverse acquisition with Life Sciences as the acquirer and Chay as the acquired party. The business and financial information included in this report is the business and financial information of Life Sciences. The accumulated deficit of Chay has been included in additional paid-in capital. Subsequent to the Merger, Chay Enterprises, Inc. was renamed Ampio Pharmaceuticals, Inc.

On March 23, 2011, Ampio acquired BioSciences (the BioSciences Merger). BioSciences' principal asset consisted of the worldwide rights to Zertane, as to which BioSciences held 32 issued patents and 31 pending patent applications. Zertane is a repurposed drug to treat male sexual dysfunction pertaining to premature ejaculation (PE) in men.

Ampio's activities, being primarily research and development and raising capital, have not generated significant revenue to date. Ampio is considered to be a development stage company.

Note 2 Formation of Subsidiary

On January 24, 2013, Ampio formed a wholly-owned subsidiary, Luoxis, to focus on the development and commercialization of the Oxidation Reduction Potential (ORP) technology platform. The ORP technology indicates disease severity and progression across a wide range of critical and chronic illnesses.

Luoxis was funded through a private placement launched on February 15, 2013. On March 15, 2013, an initial closing was completed and two additional closings were completed on April 30 and May 31, 2013. A total of 4,652,500 shares were issued at \$1.00 per share resulting in \$4,652,500 of gross proceeds. Net proceeds were \$3,980,290 after placement agent and legal fees. The placement agent also received 465,250

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

warrants to purchase Luoxis common stock valued at \$313,064 in connection with the closing, which amount has been included in total offering costs in the consolidated statement of changes in stockholders' equity (deficit). The warrants have a term of 5 years and an exercise price of \$1.00. The warrants were issuable at the final closing and exercisable one year thereafter. Concurrent with the March 15, 2013 closing, \$330,000 was paid to Trauma Research LLC and 50,000 shares of Luoxis common stock valued at \$50,000 was issued to Institute for Molecular Medicine, Inc., both related parties, for assignment of all patents previously licensed by Ampio. The patents will be amortized over an overall estimated life of 15 years.

Table of Contents

As a result of the private placement closings, on June 30, 2013, Ampio owns 80.9% of Luoxis. The consolidated financial statements include Luoxis since Ampio has a controlling financial interest, however, the third-party holdings (19.1%) are referred to as non-controlling interests. The Luoxis cash balance included in the consolidated financial statements at June 30, 2013 totaled \$2,913,701.

Note 3 License Agreement/Revenue Recognition

During 2011, Ampio entered into a license, development and commercialization agreement with a major Korean pharmaceutical company. The agreement grants the pharmaceutical company exclusive rights to market Zertane in South Korea for the treatment of PE and for a combination drug to be developed, utilizing Zertane and an erectile dysfunction drug.

Upon signing of the agreement, Ampio received a \$500,000 upfront payment, the net proceeds of which were \$417,500 after withholding of Korean tax. The upfront payment has been deferred and is being recognized as license revenue over a ten year period. Milestone payments of \$3,200,000 will be earned and recognized contingent upon achievement of regulatory approvals and cumulative net sales targets, which may take several years. In addition, Ampio will earn a royalty based on 25% of net sales, as defined, if the royalty exceeds the transfer price of the Zertane product. No royalties have been earned to date.

Note 4 Derivative Financial Instruments

Ampio issued senior convertible unsecured debentures and related warrants in five tranches between August 2010 and January 2011 (the Senior Convertible Debentures). On February 28, 2011, Ampio's Senior Convertible Debentures were converted to 1,281,852 shares of common stock. The related warrants and the components of warrant derivative liability as reflected in the balance sheet as of June 30, 2013 and December 31, 2012 are as follows:

	June 30, 2013		December 31, 2012	
	Indexed Shares	Fair Values	Indexed Shares	Fair Values
Ampio's financings giving rise to derivative financial instruments:				
Warrants (dates correspond to hybrid financing):				
Tranche 1 - August 10, 2010	51,215	\$ 206,040	51,215	\$ 116,635
Tranche 2 - October 22, 2010-October 29, 2010				
Tranche 3 - November 12, 2010-November 29, 2010	62,345	314,421	66,434	195,813
Tranche 4 - December 13, 2010-December 29, 2010	9,051	37,582	13,686	33,913
Tranche 5 - January 20, 2011-January 31, 2011	29,344	63,929	29,344	38,410
	151,955	\$ 621,972	160,679	\$ 384,771

Ampio elected to measure the Senior Convertible Debentures at fair value in their entirety, rather than bifurcating the conversion option. The fair value of the hybrid debt instrument comprises the present value of the principal and coupon enhanced by the conversion option. Both the warrants and the conversion options embedded in the hybrid debt instruments were valued using a binomial-lattice-based valuation model. The lattice-based valuation technique was utilized because it embodies all of the requisite assumptions (including the underlying price, exercise price, term, volatility, and risk-free interest-rate) that are necessary to fair value these instruments. For forward contracts that contingently require net-cash settlement as the principal means of settlement, Ampio projects and discounts future cash flows applying probability-weighting to multiple possible outcomes. Estimating fair values of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the trading market price of Ampio's common stock, which has a high-historical volatility. Since derivative financial instruments are initially and subsequently carried at fair value, Ampio's income will reflect the volatility in these estimate and assumption changes.

Table of Contents

The following table summarizes the effects on Ampio's unrealized loss associated with the warrants recorded at fair value by type of financing for the three and six months ended June 30, 2013 and 2012, respectively:

	Three Months Ended June 30, 2013	Three Months Ended June 30, 2012	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012
Warrants (dates correspond to financing)				
Tranche 1 - August 10, 2010	\$ 88,130	\$ 70,116	\$ 89,405	\$ 21,837
Tranche 2 - October 22, 2010-October 29, 2010		9,794		3,205
Tranche 3 - November 12, 2010-November 29, 2010	34,033	112,595	131,110	37,329
Tranche 4 - December 13, 2010-December 29, 2010	5,131	19,234	19,833	6,490
Tranche 5 - January 20, 2011-January 31, 2011	12,095	21,487	25,519	7,386
	\$ 139,389	\$ 233,226	\$ 265,867	\$ 76,247

Note 5 Fair Value Considerations

Ampio's financial instruments include cash and cash equivalents, accounts payable and warrant derivative liability. The carrying amounts of cash and cash equivalents, and accounts payable approximate their fair value due to their short maturities. Derivative financial instruments, as defined by GAAP, consist of financial instruments or other contracts that contain a notional amount and one or more underlying (e.g. interest rate, security price or other variable), require no initial net investment and permit net settlement. Derivative financial instruments may be free-standing or embedded in other financial instruments. Further, derivative financial instruments are initially, and subsequently, measured at fair value and recorded as liabilities or, in rare instances, assets, with changes in fair value recorded in earnings.

Ampio generally does not use derivative financial instruments to hedge exposures to cash-flow, market or foreign-currency risks. However, Ampio has entered into certain other financial instruments and contracts, such as Ampio's previously outstanding secured convertible debenture and warrant financing arrangements that are either (i) not afforded equity classification, (ii) embody risks not clearly and closely related to host contracts, or (iii) may be net-cash settled by the counterparty. As required by GAAP, these instruments are required to be carried as derivative liabilities, at fair value, in Ampio's financial statements. However, Ampio may elect fair value measurement of the hybrid financial instruments, on a case-by-case basis, rather than bifurcate the derivative. Ampio believes that fair value measurement of the hybrid convertible debenture financing arrangements provide a more meaningful presentation.

Authoritative guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. The guidance establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of Ampio. Unobservable inputs are inputs that reflect our assumptions of what market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. The hierarchy is broken down into three levels based on reliability of the inputs as follows:

- Level 1: Inputs that reflect unadjusted quoted prices in active markets that are accessible to Ampio for identical assets or liabilities;
- Level 2: Inputs include quoted prices for similar assets and liabilities in active or inactive markets or that are observable for the asset or liability either directly or indirectly; and
- Level 3: Unobservable inputs that are supported by little or no market activity.

Ampio's assets and liabilities which are measured at fair value are classified in their entirety based on the lowest level of input that is significant to their fair value measurement. Ampio's policy is to recognize transfers in and/or out of fair value hierarchy as of the date in which the event or change in circumstances caused the transfer. Ampio has consistently applied the valuation techniques discussed below in all periods presented.

Table of Contents

The following table presents Ampio's financial liabilities that were accounted for at fair value on a recurring basis as of June 30, 2013 and December 31, 2012, by level within the fair value hierarchy:

	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
June 30, 2013				
LIABILITIES				
Warrant derivative liabilities			\$ 621,972	\$ 621,972
December 31, 2012				
LIABILITIES				
Warrant derivative liabilities			\$ 384,771	\$ 384,771

The warrant derivative liability for the warrants associated with debt was valued using the binomial lattice-based valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. Significant assumptions in valuing the warrant liability were as follows as of June 30, 2013 and December 31, 2012:

	June 30, 2013	December 31, 2012
Warrants (All Tranches):		
Exercise price	\$1.75	\$1.75
Volatility	138.75%	148.60%
Equivalent term (years)	0.11 - 0.59	0.61 - 1.08
Risk-free interest rate	0.10%	0.16%

The following table sets forth a reconciliation of changes in the fair value of financial liabilities classified as Level 3 in the fair valued hierarchy:

	Derivative and Hybrid Debt Instruments
Balance as of December 31, 2012	\$ (384,771)
Total realized losses:	
Included in earnings	(265,867)
Warrant exercises	28,666
Balance as of June 30, 2013	\$ (621,972)

Note 6 Commitments and Contingencies

Commitments and contingencies are described below and summarized by the following table:

	Total	Due in Less than 1 Year	Due 1-3 Years	Due 3-5 Years	More than 5 Years
Clinical research and trial obligations	\$ 6,737,423	\$ 6,737,423	\$	\$	\$
Sponsored research agreement with related party	\$ 307,708	\$ 263,750	\$ 43,958	\$	\$
Office lease	\$ 119,344	\$ 110,148	\$ 9,196	\$	\$
Officers employment agreements	\$ 870,104	\$ 441,354	\$ 428,750	\$	\$

\$ 8,034,579	\$ 7,552,675	\$ 481,904	\$	\$
--------------	--------------	------------	----	----

Clinical Research and Trial Obligations

In connection with clinical trials for Ampion and Optina, both of which began in the first quarter of 2013, Ampio has remaining commitments of \$916,571 on contracts related to the Ampion clinical trial and \$5,820,852 on contracts related to the Optina clinical trial.

Table of Contents***Sponsored Research Agreement with Related Party***

Ampio entered into a Sponsored Research Agreement with Trauma Research LLC, a related party, in September 2009. Under the terms of the Sponsored Research Agreement, Ampio is to provide personnel and pay for leased equipment. The Sponsored Research Agreement may be terminated without cause by either party on 180 day notice.

Leases

On May 20, 2011, Ampio entered into a 38 month non-cancellable operating lease for office space effective June 1, 2011. Commitments include the annual operating expense increase for 2013. Rent expense for the respective periods are as follows:

	Three Months Ended		Six Months Ended	
	June 30,	June 30,	June 30,	June 30,
	2013	2012	2013	2012
Rent expense	\$ 29,118	\$ 25,398	\$ 58,678	\$ 50,796

Employment Agreements

As of June 30, 2013, Ampio has employment agreements with four of its executive officers. Under the employment agreements, the executive officers are collectively entitled to receive \$955,000 in annual salaries. The employment agreements expire July 31, 2013 with respect to our chief scientific officer and chief regulatory affairs officer, January 2015 with respect to our chief executive officer and December 2015 with respect to our chief operating officer. The portion of the salary due to our chief scientific officer that is included in the Sponsored Research Agreement with Trauma Research LLC is excluded from the officers' employment agreements commitment. See Note 10 Subsequent Event regarding the extension of the two contracts which expire July 31, 2013.

Note 7 Common Stock***Capital Stock***

At June 30, 2013 and December 31, 2012, Ampio had 100,000,000 shares of common stock authorized with a par value of \$0.0001 per share and 10,000,000 shares of preferred stock authorized with a par value of \$0.0001 per share.

Shelf Registration

On September 30, 2011, Ampio filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission to register Ampio common stock and warrants in an aggregate amount of up to \$80 million for offering from time to time in the future. The registration statement also registers for possible resale up to one million shares of common stock to be sold by directors and management (as selling shareholders) in future public offerings. On October 13, 2011 Ampio filed an amendment to identify potential selling stockholders and the number of shares they would be eligible to sell in the event of a future public offering. The shelf registration was declared effective on October 28, 2011 by the Securities and Exchange Commission. At June 30, 2013, Ampio had \$53.7 million available for future public offerings along with 714,900 shares remaining for future sale by named selling shareholders.

Underwritten Public Offering

On July 18, 2012, Ampio completed an underwritten public offering for the sale of 5,203,860 shares of common stock at a price of \$3.25 per share. Gross proceeds to the Company were \$16,912,545 with net proceeds of \$15,353,150 after underwriter fees and cash offering expenses. Ampio also issued warrants to purchase 138,462 shares of common stock to the underwriters. These warrants have an exercise price of \$4.0625 and can be exercised from the period July 12, 2013 through July 12, 2017.

Registered Direct Offering

On December 27, 2011, Ampio completed a registered direct offering of its common stock. A total of 2,220,255 shares were issued at \$4.25 per share resulting in gross proceeds of \$9,436,084, of which Ampio received net proceeds of \$8,454,001, after placement agent commissions,

non-accountable expenses and other offering costs.

Table of Contents**Private Placement Offering**

On March 31, April 8 and April 18, 2011, Ampio closed private placements of its common stock (the 2011 Private Placement). A total of 5,092,880 shares of common stock were issued resulting in gross proceeds of \$12,732,200, of which the Company received net proceeds of \$10,916,538, after placement agent commissions, non-accountable expenses and other offering costs. In connection with the private placements, the placement agent also received 509,288 warrants to purchase common stock with a fair value of \$888,664.

Note 8 Equity Instruments**Options**

Ampio adopted a stock plan in March 2010. The number of shares of common stock reserved for issuance to officers, directors, employees and consultants through various means, including incentive stock options, non-qualified stock options, restricted stock grants, and other forms of equity equivalents is currently 8,200,000 shares.

Ampio has computed the fair value of all options granted using the Black-Scholes option pricing model. In order to calculate the fair value of the options, certain assumptions are made regarding components of the model, including the estimated fair value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield and expected option life. Changes to the assumptions could cause significant adjustments to valuation. Ampio estimated a volatility factor utilizing a weighted average of comparable published volatilities of peer companies. Ampio has estimated a forfeiture rate of zero as the effect of forfeitures has not been significant and the small number of option holders does not provide a reasonable basis for prediction. Ampio estimates the expected term based on the average of the vesting term and the contractual term of the options. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. Ampio has computed the fair value of all options granted during the six months ended June 30, 2013 using the following assumptions:

Expected volatility	70% - 89%
Risk free interest rate	0.40% - 1.27%
Expected term (years)	3.0 - 6.5
Dividend yield	0%

Ampio Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Fair Value
Outstanding December 31, 2011	3,832,874	\$ 2.75	7.31	\$ 3,443,616
Granted	2,095,000	\$ 2.97		
Exercised	(715,476)	\$ (1.07)		
Forfeited	(256,250)	\$ (4.04)		
Expired	(33,333)	\$ (5.96)		
Outstanding December 31, 2012	4,922,815	\$ 2.25	8.36	\$ 7,132,347
Granted	220,000	\$ 4.17		
Exercised	(54,584)	\$ 2.35		
Forfeited	(64,581)	\$ 4.11		
Outstanding June 30, 2013	5,023,650	\$ 2.35	7.72	\$ 7,412,723
Exercisable at June 30, 2013	3,794,763	\$ 1.98	7.00	\$ 4,090,537

Table of Contents

Pursuant to the Luoxis 2013 Stock Option Plan (the 2013 Plan), 5,000,000 shares of its common stock was reserved for issuance under the 2013 Plan. On June 15, 2013, Luoxis granted 1,800,000 shares to officers, employees and consultants. The shares have an exercise price of \$1.00 which is the same as the private placement offering price. Twenty-five percent of the shares vested immediately and the remainder vest annually on the grant date at a rate of 25% over the next three years. The fair value of these options totaling \$1,272,366 were also calculated using the Black-Scholes option pricing model utilizing the same methodology as described above for Ampio including the following assumptions:

Expected volatility	86%
Risk free interest rate	1.04% - 1.53%
Expected term (years)	5.0 - 6.5
Dividend yield	0%

Luoxis Stock option activity is as follows:

	Number of Options	Exercise Price	Remaining Contractual Life	Aggregate Fair Value
Granted	1,800,000	\$ 1.00		
Outstanding June 30, 2013	1,800,000	\$ 1.00	9.96	\$ 1,272,366
Exercisable at June 30, 2013	450,000	\$ 1.00	9.96	\$ 303,492
Available for grant at June 30, 2013	3,200,000			

Stock-based compensation expense related to the fair value of stock options was included in the statement of operations as research and development expenses and general and administrative expenses as set forth in the table below. Ampio determined the fair value as of the date of grant using the Black-Scholes option pricing method and expenses the fair value ratably over the vesting period.

The following table summarizes stock-based compensation expense for the three and six months ended June 30, 2013 and 2012:

	Three Months Ended		Six Months Ended	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
Research and development expenses				
Stock options				
Ampio	\$ 223,680	\$ 118,313	\$ 378,371	\$ 175,616
Luoxis	\$ 202,495	\$	\$ 202,495	\$
General and administrative expenses				
Common stock issued for services			88,050	40,000
Stock options				
Ampio	231,695	213,307	675,483	356,245
Luoxis	114,454		114,454	
	\$ 772,324	\$ 331,620	\$ 1,458,853	\$ 571,861
Unrecognized expenses at June 30, 2013				
Ampio	\$ 2,633,612			
Luoxis	\$ 955,417			

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

Weighted average remaining years to vest

Ampio	1.95
Luoxis	2.96

Table of Contents**Warrants**

Ampio issued warrants in conjunction with its Senior Convertible Debentures, 2011 Private Placements and an underwritten public offering as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding December 31, 2011	677,008	\$ 2.78	3.69
Warrants exercised - Debenture holders	(7,041)	\$ (1.75)	
Warrants exercised - Private Placement	(54,058)	\$ (3.13)	
Warrants issued in connection with Underwritten Offering	138,462	\$ 4.06	
Outstanding December 31, 2012	754,371	\$ 3.00	3.01
Warrants exercised - Debenture holders	(8,724)	\$ 1.75	
Outstanding June 30, 2013	745,647	\$ 3.00	2.53

The exercise price of the warrants associated with the Senior Convertible Debentures was fixed at \$1.75 per share and the warrants expire on December 31, 2013. Warrants issued in connection with the 2011 Private Placements are at \$3.125 per share and expire March 31, 2016.

In July 2012, Ampio issued warrants to purchase 138,462 shares of common stock at a price of \$4.0625, exercisable from July 12, 2013 through July 12, 2017 in connection with the underwritten public offering. In connection with the final closing of the Luoxis private placement in May 2013, Luoxis issued warrants to purchase 465,250 shares of common stock at a price of \$1.00 exercisable one year after the final closing. The weighted average remaining contractual life is 5 years. These warrants were valued using the Black-Scholes option pricing model. In order to calculate the fair value of the warrants, certain assumptions were made regarding components of the model, including the closing price of the underlying common stock, risk-free interest rate, volatility, expected dividend yield, and expected life. Changes to the assumptions could cause significant adjustments to valuation. The Company estimated a volatility factor utilizing a weighted average of comparable published volatilities of peer companies. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. The offering costs and the additional paid-in capital for the warrants associated with the common stock offering was valued at \$313,064 using the Black-Scholes valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. Significant assumptions in valuing the Luoxis warrants were as follows:

Expected volatility	87%
Risk free interest rate	0.52%
Expected term (years)	5
Dividend yield	0%

Note 9 Related Party Transactions

Ampio had license agreements with the Institute for Molecular Medicine, Inc. (IMM), a nonprofit research organization founded by an officer and director of Ampio who also serves as IMM s executive director. The license agreements were assigned to Life Sciences as a part of the asset purchase from BioSciences. Under the license agreements, Ampio paid the costs associated with maintaining intellectual property subject to the license agreements. As further noted in Note 2, the intellectual property associated with the license agreements were assigned to Luoxis and the license agreements are no longer applicable to Ampio.

In June 2013, Luoxis entered into an agreement with Trauma Research LLC (TRLLC), a related party controlled by Dr. David Bar-Or, a director and officer of Ampio. The agreement provides for Luoxis to pay \$5,834 per month to TRLLC in consideration for services related to research and development of the Luoxis Oxidation-Reduction Potential platform.

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

Immediately prior to the Chay Merger on March 2, 2010, Chay accepted subscriptions for an aggregate of 1,325,000 shares of common stock from six officers and employees of Life Sciences, for a purchase price of \$150,183. The purchase price was advanced to the six officers and employees by Chay at the time the subscriptions were accepted. These shares were issued immediately before the closing of the Chay Merger but after the shareholders of Chay had approved the merger. The advances are non-interest bearing and due on demand and are classified as a reduction to stockholders' equity. During the year ended December 31, 2011, one advance of \$22,660 was repaid. During the three months ended March 31, 2012 an additional repayment of \$36,883 was received.

Table of Contents

Note 10 Subsequent Event

On July 15, 2013, Ampio extended the Employment Agreements of Dr. David Bar-Or, Chief Scientific Officer, and Dr. Vaughan Clift, Chief Regulatory Affairs Officer, for one additional year, expiring July 31, 2014. In connection with this Amendment, Dr. Bar-Or and Dr. Clift were awarded 300,000 and 170,000 options, respectively, for Ampio common stock at an exercise price of \$6.15 with 50% vesting upon grant and 50% after one year.

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion should be read in conjunction with Ampio Pharmaceuticals, Inc.'s historical financial statements filed with this report. The following discussion and analysis contain forward-looking statements that involve risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. For additional information regarding these risks and uncertainties, please see Part II, Item 1A of this Form 10-Q, Risk Factors, and the risk factors included in Ampio's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2013.

Overview

Ampio maintains an Internet website at www.ampiopharma.com. Information on or linked to the Company website is not incorporated by reference into this Quarterly Report on Form 10Q. Filings with the SEC can also be obtained at the SEC's website, www.sec.gov.

We are a development stage biopharmaceutical company focused on the rapid development of therapies to treat prevalent inflammatory conditions for which there are limited treatment options. We are primarily focused on providing medicines to improve the health and quality of life of patients with minimal side effects. We are developing compounds that decrease inflammation by (i) inhibition of specific pro-inflammatory compounds by affecting specific pathways at the protein expression and at the transcription level or (ii) activation of a specific phosphatase or depletion of the available phosphate needed for the inflammation process and (iii) decreasing vascular permeability an upstream event in the inflammation cascade. We are also focused on monetizing our sexual dysfunction portfolio and a diagnostic device.

Acquisition

On March 23, 2011, we acquired all of the outstanding stock of DMI BioSciences, Inc. (BioSciences) for 8,667,905 shares of our common stock (the merger stock). We acquired BioSciences in order to obtain all rights to Zertane, BioSciences' male sexual dysfunction drug for premature ejaculation (PE). The business combination occurred following the satisfaction or waiver of all conditions to closing. As called for in the merger agreement, Ampio issued 405,066 shares of merger stock to holders of BioSciences in-the-money stock options and warrants, 500,000 shares of merger stock to holders of two BioSciences promissory notes in extinguishment of the notes, and placed 250,000 shares of merger stock in an indemnification escrow until December 31, 2011. The remaining 7,512,839 shares of merger stock were issued to the holders of BioSciences common stock on a pro rata basis. As required by the merger agreement, at the closing BioSciences donated back to Ampio's capital 3,500,000 shares of Ampio common stock formerly owned by BioSciences. Ampio separately issued 212,693 options in replacement of 250,850 Biosciences options that were out-of-the-money as of the date of execution of the merger agreement. On June 17, 2011, an additional 223,024 options were issued in exchange for 98,416 previously issued shares of Ampio stock pursuant to an agreement with three former BioSciences option holders. During 2011, we filed a claim on the indemnification escrow and were awarded 95,700 shares of Ampio stock to reflect the full value of the 223,024 options issued in exchange for the shares relinquished. On December 31, 2011 the remaining 154,300 indemnification escrow shares were allocated to the appropriate shareholders. All shares donated back, relinquished and escrow shares awarded to Ampio have been cancelled.

Financing History/Overview

On February 28, 2011, we issued an aggregate of 1,281,852 shares of our common stock in retirement of the Senior Convertible Debentures issued to 21 holders of such debentures. The convertible debentures were previously issued in five tranches. The first tranche consisted of \$430,000 in principal amount issued in August 2010 to two directors and an affiliate of one of those directors. The next three tranches consisted of \$1.38 million in principal amount issued in October, November and December 2010 to 19 unaffiliated holders (seven of whom were already our shareholders), and the remaining tranche in January 2011 was an increase of \$382,000 in principal amount of debentures purchased by five holders who originally purchased debentures in November 2010. The principal amount of the debentures and accrued interest were converted into our common stock at \$1.75 per share. Debentures held by two directors and an affiliate of one director were converted on the same terms as debentures held by unaffiliated parties. The debenture holders were collectively issued warrants to purchase 256,389 shares of our common stock as additional consideration for the purchase of the debentures. Those warrants are exercisable at \$1.75 per share.

On March 31, April 8 and April 18, 2011, we closed private placements of our common stock (the 2011 Private Placement). A total of 5,092,880 shares of common stock were issued resulting in gross proceeds of \$12,732,200, of which we received net proceeds of \$10,916,538, after placement agent commissions, non-accountable expenses and other offering costs. The placement agent also received 509,288 warrants valued at \$888,664 in connection with the closing. We applied a portion of the private placement proceeds in March and April 2011 to pay accrued expenses, to pay accrued salaries owed to certain of our officers, to reduce accounts payable, and to repay a \$100,000 promissory note to Michael Macaluso, our chief executive officer and chairman of the board.

Table of Contents

In September 2011, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission to register our common stock and warrants in an aggregate amount of up to \$80 million for offering from time to time in the future. The registration statement also registers for possible resale up to one million shares of common stock to be sold by directors and management (as selling shareholders) in future public offerings. On October 13, 2011 we filed an amendment to identify potential selling shareholders and the number of shares they would be eligible to sell in the event of a future public offering. The shelf registration was declared effective on October 28, 2011 by the Securities and Exchange Commission. At June 30, 2013 Ampio had \$53.7 million available for future public offerings along with 714,900 shares remaining for future sale by named selling shareholders.

In December 2011, we completed a registered direct offering of our common stock. A total of 2,220,255 shares were issued at a price of \$4.25 per share resulting in gross proceeds of \$9,436,084, of which we received net proceeds of \$8,454,001, after placement agent commissions, non-accountable expenses and other offering costs. No warrants were issued.

In July 2012, we completed an underwritten public offering for the sale of 5,203,860 shares of common stock at a price of \$3.25 per share. Gross proceeds to Ampio were \$16,912,545 with net proceeds of \$15,353,150 after underwriter fees and cash offering expenses. We also issued warrants to purchase 138,462 shares of common stock to the underwriters. These warrants have an exercise price of \$4.0625 and can be exercised from the period July 12, 2013 through July 12, 2017. Certain shareholders also became selling shareholders and received gross proceeds of \$926,575 from the offering of 285,100 shares as provided in the registration statement.

The net proceeds of the above offerings have been or will be used for general corporate purposes and working capital, including the continued progress of research and development of our product candidates, the completion of clinical trials and regulatory approvals, and preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights.

In January 2013, we formed a subsidiary, Luoxis Diagnostics, Inc. (Luoxis) to focus on the development and commercialization of our Oxidation Reduction Potential (ORP) technology platform. Luoxis was funded through a private placement which had a final closing on May 31, 2013 with \$4,652,500 in gross proceeds. Net proceeds were \$3,980,290 after placement agent and legal fees. Prior to the private placement, Ampio incurred all of the costs associated with the development of the ORP platform. As a result of the private placement, Ampio now owns 80.9% of Luoxis Diagnostics.

Product Update

We continue to execute our business plan and have moved forward on our three main drug candidates and our device development.

Ampion for Osteoarthritis of the Knee

In December 2012, we submitted an IND to the FDA for the Phase 3 pivotal trial based upon the guidance received at the pre-IND meeting with the FDA in May 2012. Our prior IND submission and FDA guidance suggested we would complete two Phase 3 studies (AP-003 and AP-004) with respect to Ampion, each enrolling approximately 800 patients. In February 2013, we received new formal guidance from the FDA indicating that the Company should conduct a dose ranging study as a Phase 2 dose-escalation study or as a run-in study for one of the Phase 3 studies. Accordingly, we submitted an updated trial protocol to the FDA and they approved it in late March. Known as the SPRING trial, Ampion is being evaluated for its effect on reducing pain as a single intra-articular injection into the knee in 4 milliliter (mL) and 10 milliliter (mL) volumes as compared to placebo at twelve weeks. The study enrolled in excess of the targeted 320 patient goal. The study was designed as a run-in to a Phase 3 pivotal trial which we will initiate once the optimal volume is determined and the proposed pivotal trial is properly powered to achieve its scientific objectives. In April 2013, we announced the completion of patient enrollment in the SPRING trial. Twelve week primary endpoint data are expected in the third quarter of 2013.

Optina for Diabetic Macula Edema

The FDA granted Optina™ 505(b)(2) status in July, 2012, and we commenced enrollment in the clinical trial in February 2013. Drugs designated under this pathway can be approved on a single trial. The multicenter trial is designed to evaluate the safety and efficacy of oral Optina compared with placebo given over a period of 12 weeks in adult patients with DME. Patients will be randomized to receive one of two doses of Optina (0.5mg per BMI and 1.0mg per BMI per day) or placebo. After patients have completed 4 weeks of initial treatment, an interim analysis will occur to determine the best dose of Optina. Following the 12 week active treatment period, there will be a further 4 week washout period to determine regression of treatment effect. The primary endpoint is improvement in visual acuity (VA), defined by responder status, compared to placebo. Secondary endpoints are (i) measurements of changes in VA and central macular thickness (CMT) in treated patients compared to placebo, and (ii) safety and tolerability of the two Optina doses. Following treatment and washout, patients will be assessed for vision regression and a 12 week open label extension study will be offered to evaluate the duration of effect of the optimal dose. A total of 450

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

patients are expected to enroll. On February 27, 2013, we announced oral dosing of the first patient in the Optina Trial.

Table of Contents

Zertane for Male Sexual Dysfunction

In March 2013, we announced the FDA's acceptance of our Patient Outcome for Premature Ejaculation (POPE) questionnaire, a modification of the questionnaire that was used in the two successful Zertane Phase 3 clinical trials completed in Europe. The acceptance by the FDA of the POPE questionnaire allows us, or a partner, to file an IND with the FDA for a pivotal trial of Zertane.

In June 2013, Ampio submitted the application to the Therapeutic Goods Administration (TGA) for approval of Zertane in Australia. The Company expects to receive marketing authorization in the first half of 2014. An approval in Australia will open up numerous markets worldwide including South Korea and Brazil where Ampio has licensing agreements. This could also be important for additional business negotiations and revenue for Ampio.

ORP, Point-of-Care Diagnostic Device

In January 2013, we formed a subsidiary, Luoxis, to focus on the development and commercialization of our Oxidation Reduction Potential (ORP) technology platform. All technology and patents related to the ORP technology platform have been assigned to Luoxis. The final funding of operations was through a private placement completed on May 31, 2013 for net proceeds of \$3,980,290 representing a 19.1% non-controlling interest.

In June 2013, Luoxis announced positive summary data from the first clinical trial using the oxidation-reduction potential (ORP) diagnostic platform. The results are reported from a prospective clinical trial of 153 elderly hip fracture patients who suffered their hip fractures as a result of a fall, the most common cause of hip fractures among the elderly. When studying the markers measured by the ORP diagnostic system, investigators demonstrated statistically significant correlations between patients' antioxidant reserve levels and established comorbidity measures ($p=0.02$). Investigators also reported a statistically significant correlation between patients' oxidation-reduction potential levels and injury severity as measured by the validated Injury Severity Score (ISS; $p=0.01$). These clinical study results confirm the predictive value of oxidation-reduction potential and antioxidant reserves and their validity as prognostic markers among elderly hip fracture patients in a clinical setting.

Known Trends or Future Events

We have not generated any significant revenues and have therefore incurred significant net losses totaling \$50.1 million since our inception in December 2008. The assets we purchased from BioSciences in April 2009 generated minimal revenues prior to their acquisition. Although we have raised capital in the past and raised net proceeds of \$4.0 million, \$15.4 million and \$19.4 million through the sale of common stock in 2013, 2012 and 2011, respectively, we cannot assure you that we will be able to secure such additional financing, if needed, or that it will be adequate to execute our business strategy. Even if we obtain additional financing, it may be costly and may require us to agree to covenants or other provisions that will favor new investors over existing shareholders.

We expect to incur losses from operations for the foreseeable future. We expect to incur substantial research and development expenses, including expenses related to clinical trials for Ampion and Optina. We also intend to limit the extent of these losses by entering into co-development, collaboration agreements or a sale with one or more strategic partners for our sexual dysfunction portfolio and the monetization of ORP either through a sale or an initial public offering of Luoxis. At this time, due to the risks inherent in the clinical trials and the stage of development of our product candidates, we are unable to estimate with any certainty the additional costs we will incur for the continued development of our product candidates for commercialization as clinical development timelines, probability of success, and development costs vary widely.

Significant Accounting Policies and Estimates

Our financial statements have been prepared in accordance with accounting policies generally accepted in the United States of America. The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to recoverability of long-lived assets, fair value of our derivative instruments, allowances and contingencies. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The methods, estimates, and judgments used by us in applying these most critical accounting policies have a significant impact on the results we report in our financial statements.

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

Our significant accounting policies and estimates are included in our 2012 Annual Report reported on form 10-K, filed with the SEC on March 6, 2013. During the first six months of 2013, there were no significant changes to our significant accounting policies and estimates.

Table of Contents**Results of Operations June 30, 2013 Compared to June 30, 2012**

Results of operations for the three months ended June 30, 2013 (the 2013 quarter) and the three months ended June 30, 2012 (the 2012 quarter) reflected losses of approximately \$6,593,000 and \$2,496,000, respectively. These losses include non-cash income and charges related to derivative income/expense, stock based compensation, common stock issued for services and depreciation and amortization in the amount of \$951,000 in the 2013 quarter and \$580,000 in the 2012 quarter.

Results of operations for the six months ended June 30, 2013 (the 2013 period) and the six months ended June 30, 2012 (the 2012 period) reflected losses of approximately \$10,802,000 and \$5,332,000, respectively. These losses include non-cash charges related to derivative expense/income, stock based compensation, common stock issued for services and depreciation and amortization in the amount of \$1,782,000 in the 2013 period and \$679,000 in the 2012 period.

Revenue

We are a development stage enterprise and have not generated material revenue in our operating history. The \$25,000 license revenue recognized in the 2013 period and 2012 period represents the amortization of the upfront payment received on our license agreement. The initial payment of \$500,000 from the license agreement of Zertane with a Korean pharmaceutical company was deferred and will be recognized over 10 years.

Expenses*Research and Development*

Research and development costs are summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Labor	\$ 346,000	\$ 336,000	\$ 664,000	\$ 733,000
Patent costs	512,000	323,000	974,000	676,000
Stock-based compensation	426,000	119,000	581,000	176,000
Clinical trials and sponsored research	3,886,000	730,000	5,570,000	1,198,000
Consultants	79,000	43,000	247,000	241,000
	\$ 5,249,000	\$ 1,551,000	\$ 8,036,000	\$ 3,024,000

Research and development costs consist of labor, research and development of patents and intellectual property, stock-based compensation as well as drug development and clinical trials. Costs of research and development increased \$3,698,000, or 238%, for the 2013 quarter compared to the 2012 quarter and \$5,012,000, or 166%, for the 2013 period compared to the 2012 period. The increases are principally the result of clinical trials for Ampion and Optina, and the Luoxis development of its ORP platform. Stock-based compensation increased due to the incremental stock options awarded in both Ampio and Luoxis and the continuing vesting of awards granted in previous years. Patent costs reflect the strengthening and ongoing maintenance of our patent portfolio.

General and Administrative

General and administrative costs are summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Labor	\$ 269,000	\$ 152,000	\$ 485,000	\$ 911,000
Stock-based compensation	346,000	213,000	878,000	396,000

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

Professional fees	114,000	102,000	284,000	233,000
Occupancy, travel and other	442,000	197,000	795,000	593,000
Directors fees	49,000	63,000	90,000	130,000
	\$ 1,220,000	\$ 727,000	\$ 2,532,000	\$ 2,263,000

General and administrative costs increased \$493,000, or 68%, for the 2013 quarter compared to the 2012 quarter. The increases are primarily due to increased professional staffing in Luoxis, stock option awards granted by Luoxis and continuing vesting of Ampio awards granted in previous years, and occupancy, travel and other. These other expenses include insurance, investor relations and recruiting. During the 2013 quarter, insurance, travel and Luoxis recruiting fees were primarily responsible for the increase in occupancy, travel and other.

Table of Contents

For the 2013 period, general and administrative costs increased \$269,000, or 12%, compared to the 2012 period primarily as a result of increases in stock-based compensation and occupancy, travel and other which were off-set by a reduction in labor due to a first quarter 2012 one-time payout to our former CEO pursuant to the terms of the employment agreement.

Derivative income (expense)

We recorded \$139,389 of non-cash derivative expense in the 2013 quarter compared to \$233,226 in the 2012 quarter and \$265,867 in the 2013 period compared to \$76,247 in the 2012 period in connection with our hybrid financial instruments consisting of debentures and related warrants. These amounts relate to the subsequent changes in fair value of the debentures issued in 2011 and 2010 stemming from the embedded derivative features (conversion options, down-round protection and mandatory conversion provisions) and the changes in fair value of warrants issued in conjunction with the debentures.

Net Cash Used in Operating Activities

During the 2013 period, our operating activities used approximately \$8.7 million in cash which was less than the net loss of \$10.6 million primarily as a result of the non-cash stock based compensation and derivative expense.

In the 2012 period, the use of cash was \$5.2 million and was slightly less than the \$5.3 million net loss principally as a result of non-cash stock-based compensation being off-set by changes in prepaid expense and accounts payable.

Net Cash Used in Investing Activities

During the 2013 period, cash was used to acquire ORP patents on behalf of Luoxis. See Note 2 Formation of Subsidiary. Fixed assets reflect purchases of a new server system, a lab scope, and a Luoxis ORP manufacturing device.

Net Cash from Financing Activities

Net cash provided by financing activities in the 2013 period of \$4.1 million reflects proceeds from the Luoxis private financings of \$4.0 million and \$0.1 million from the exercise of stock options and warrants.

In the 2012 period, net cash provided by financing activities was due to a cash exercise of stock options of \$618,000 and repayment of \$37,000 related to stockholder advances made in 2010.

Liquidity and Capital Resources

As a development stage biopharmaceutical company, we have not generated significant revenue as our primary activities are focused on research and development, advancing our primary product candidates, and raising capital. As of June 30, 2013, we had cash and cash equivalents totaling \$12.5 million and \$1.8 million in accounts payable, of which \$2.9 million of the cash and cash equivalents and \$0.1 million in payables related to Luoxis. Based upon our current expectations, we believe our capital resources at June 30, 2013 will be sufficient to fund our currently planned operations into the first quarter of 2014. This estimate is based on a number of assumptions that may prove to be wrong, and we could exhaust our available cash and cash equivalents earlier than presently anticipated. We may be required or choose to seek additional capital within the next 6 months to expand our clinical development activities for Ampion and Optina. This could be necessary either assuming positive results of our ongoing clinical trials or if we face challenges or delays in connection with those trials. Additional funding will be required for the commercial launch of Ampion and Optina. We also may choose to seek additional capital to maintain minimum cash balances that we deem reasonable and prudent. We intend to evaluate the capital markets from time to time to determine whether to raise additional capital in the form of equity, convertible debt or otherwise, depending on market conditions relative to our need for funds at such time, and we may seek to raise additional capital should we conclude that such capital is available on terms that we consider to be in the best interests of us and our stockholders.

We have prepared a budget for 2013 which reflects cash requirements for fixed, on-going expenses such as payroll, legal and accounting, patents and overhead at an average cash burn rate of between \$550,000 and \$600,000 per month. Additional funds in the amount of approximately \$6.7 million are planned for regulatory approvals and completion of clinical trials. To the extent we decide to further expand our clinical trials, it will be necessary to raise additional capital and/or enter into licensing or collaboration agreements. At this time, we expect to satisfy our future cash needs through private or public sales of our securities or debt financings. We cannot be certain that financing will be available to us on acceptable terms, or at all. In recent years, volatility in the financial markets has adversely affected the market capitalizations of many pharmaceutical companies and generally made equity and debt financing more difficult to obtain. This volatility, coupled with other factors, may

limit our access to additional financing.

Table of Contents

If we cannot raise adequate additional capital in the future when we require it, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. This may lead to impairment or other charges, which could materially affect our balance sheet and operating results.

Off Balance Sheet Arrangements

We do not have off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as variable interest entities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The Company is not currently exposed to material market risk arising from financial instruments, changes in interest rates or commodity prices, or fluctuations in foreign currencies. The Company has no need to hedge against any of the foregoing risks and therefore currently engages in no hedging activities.

Item 4. Controls and Procedures.

As of the end of the period covered by this Quarterly Report on Form 10-Q, an evaluation was carried out by the Company's management, with the participation of the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934. Based on such evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed in the reports the Company files or furnishes under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations, and are operating in an effective manner.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

The Company is currently not party to any material pending legal proceedings, whether routine or non-routine.

Item 1A. Risk Factors.

Certain factors exist which may affect the Company's business and could cause actual results to differ materially from those expressed in any forward-looking statements. The Company has not experienced any material changes from those risk factors as previously disclosed in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2013. However, the Company will continue to require additional capital, the receipt of which is not assured.

Item 2. Unregistered Sales of Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits

Exhibit

Number	Description
31.1	Certificate of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certificate of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certificate of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*.
101.INS	XBRL Instance Document+
101.SCH	XBRL Taxonomy Extension Schema Document+
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document+

Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 10-Q

101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document+
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document+

* The certification attached as Exhibit 32.1 accompanying this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, shall not be deemed filed by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

+ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AMPIO PHARMACEUTICALS, INC.

By: /s/ Michael Macaluso
Michael Macaluso
Chief Executive Officer
Date: August 9, 2013

By: /s/ Mark D. McGregor
Mark D. McGregor
Chief Financial Officer
Date: August 9, 2013