Ampio Pharmaceuticals, Inc.
Form 10-Q
May 07, 2014
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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: March 31, 2014

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)

Delaware	**26-0179592**
(State or other jurisdiction of incorporation or organization)	**(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 x 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 x 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 x
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 x

As of May 7, 2014, there were 51,916,172 shares outstanding of Common Stock, par value $0.0001, of the registrant.

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AMPIO PHARMACEUTICALS, INC.

AND SUBSIDIARIES

THREE MONTHS ENDED MARCH 31, 2014

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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 beneficial 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, Luoxis and Vyrix, 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.

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PART I FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES

(A Development Stage Company)

Consolidated Balance Sheets

	March 31, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$ 78,225,754	$ 26,309,449
Prepaid expenses	495,303	131,986
Prepaid research and development - related party (Note 9)	254,710	
Total current assets	78,975,767	26,441,435
Fixed assets, net (Note 2)	4,317,188	1,298,504
In-process research and development	7,500,000	7,500,000
Patents, net	717,260	734,957
Long-term portion of prepaid research and development - related party (Note 9)	1,074,215	
Deposits	43,856	43,856
	13,652,519	9,577,317
Total assets	$ 92,628,286	$ 36,018,752
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	$ 4,422,421	$ 1,900,576
Accrued liabilities - related party (Note 9)	600,000	
Accrued bonuses		522,056
Deferred revenue	50,000	50,000
Total current liabilities	5,072,421	2,472,632
Long-term deferred revenue	318,750	331,250
Total liabilities	5,391,171	2,803,882
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 - 51,916,172 in 2014 and 42,065,031 in 2013	5,192	4,207
Additional paid-in capital	161,435,766	96,942,744
Advances to stockholders	(90,640)	(90,640)
Deficit accumulated in the development stage	(74,021,338)	(63,779,155)
Total Ampio stockholders equity	87,328,980	33,077,156
Non-controlling interests	(91,865)	137,714
Total equity	87,237,115	33,214,870
Total liabilities and equity	$ 92,628,286	$ 36,018,752

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

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AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES

(A Development Stage Company)

Consolidated Statements of Operations

(unaudited)

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013	December 18, 2008 (Inception) through March 31, 2014
License revenue	$ 12,500	$ 12,500	$ 131,250
Expenses			
Research and development	$ 8,403,667	$ 2,786,822	$ 43,877,263
Research and development - related party (Note 9)	11,075		11,075
General and administrative	2,073,015	1,311,800	21,913,929
Total operating expenses	10,487,757	4,098,622	65,802,267
Other income (expense)			
Interest income	3,495	4,277	46,315
Interest expense			(29,317)
Unrealized loss on fair value of debt instruments			(5,547,911)
Derivative (expense) income		(126,478)	(3,234,340)
Total other income (expense)	3,495	(122,201)	(8,765,253)
Net loss, before income tax	$ (10,471,762)	$ (4,208,323)	$ (74,436,270)
Foreign tax expense			82,500
Net loss	$ (10,471,762)	$ (4,208,323)	$ (74,518,770)
Net loss applicable to non-controlling interests	$ 229,579	$ 29,695	$ 749,447
Net loss applicable to Ampio	$ (10,242,183)	$ (4,178,628)	$ (73,769,323)
Weighted average number of Ampio common shares outstanding	44,950,267	37,072,509	
Basic and diluted Ampio net loss per common share	$ (0.23)	$ (0.11)	

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

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AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES

(A Development Stage Company)

Consolidated Statements of Stockholders Equity (Deficit)

Series A Preferred Stock Shares	Series A Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Common Stock Subscribed	Additional Paid in Capital	Additional Issuances	Advances to Stockholders	Deficit Accumulated in the Development Stage	Non-controlling Interests
	$		$	$	$	$	$	$	$
		1,080,000	1,080						
		1,080,000	1,080						
		3,500,000	3,500					(252,015)	
163,934	164				199,836				
		7,350,000	7,350						
913,930	914				1,114,106				

				170,003						
									(1,512,908)	
1,077,864	$ 1,078	11,930,000	$ 11,930	$ 170,003	$ 1,313,942	$	$	$	(1,764,923)	$
(1,077,864)	(1,078)	3,068,958	(10,430)		11,691					
				7,000						
		1,078,078	108	(177,003)	1,536,522					
		1,030,000	103		1,802,397	(3,281)				
					1,297,083					
							(150,183)			
									(8,053,395)	
	$	17,107,036	$ 1,711	$	$ 5,961,635	$ (3,281)	$ (150,183)	$	(9,818,318)	$
		13,635	1		1,983,784					
						3,281				
		1,281,852	128		9,423,947					
		1,714			3,000					

301,604	30	109,015				
5,167,905	517	7,852,220				
5,092,880	509	10,916,029				
88,669	8	784,356				
(98,416)	(9)	574,009				
(95,700)	(9)	9				
				22,660		
2,220,255	222	8,453,779				
					(18,359,234)	
$ 31,081,434	$ 3,108	$	$ 46,061,783	$	$ (127,523)	$ (28,177,552) $
24,072	3	100,147				
680,809	68	617,932				
19,520	2	32,692				
		1,522,374				

				36,883			
5,203,860	520		15,352,630				
					(11,593,045)		
$ 37,009,695	$ 3,701	$	$ 63,687,558	$	$ (90,640)	$ (39,770,597)	$
22,752	2		88,048				
4,600,319	460		25,003,526				
			3,340,937				639,353
			42,510				7,490
			(10,739)				10,739
238,381	24		159,858				
193,884	20		1,182,761				
			3,448,285				
						(24,008,558)	(519,868)

$	42,065,031	$ 4,207	$	$ 96,942,744	$	$ (90,640)	$ (63,779,155)	$ 137,714
	4,209			30,000				
	9,775,000	979		63,424,244				
	64,425	6		17,547				
	7,507							
				1,021,231				
							(10,242,183)	(229,579)
$	51,916,172	$ 5,192	$	$ 161,435,766	$	$ (90,640)	$ (74,021,338)	$ (91,865)

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

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AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES

(A Development Stage Company)

Consolidated Statements of Cash Flows

(unaudited)

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013	December 18, 2008 (Inception) through March 31, 2014
Cash flows from operating activities:			
Net loss	$ (10,471,762)	$ (4,208,323)	$ (74,518,770)
Depreciation and amortization	41,216	18,463	283,843
Amortization of prepaid research and development - related party (Note 9)	11,075		11,075
Common stock issued for services	30,000	88,050	2,020,700
Stock-based compensation expense	1,021,231	598,479	9,272,758
Derivative expense		126,478	3,234,340
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	(363,317)	(185,500)	(495,303)
(Increase) in prepaid research and development - related party (Note 9)	(1,340,000)		(1,340,000)
Increase in related party payable			109,789
Increase (Decrease) in accounts payable	2,521,845	(31,322)	4,422,423
Increase in accrued liabilities - related party (Note 9)	600,000		600,000
Increase (Decrease) in deferred revenue	(12,500)	(12,500)	368,750
(Decrease) in accrued bonuses/salaries	(522,056)		
Increase in accrued interest payable			16,948
Net cash used in operating activities	(8,484,268)	(3,606,175)	(50,465,536)
Cash flows used in investing activities:			
Purchase of fixed assets	(3,042,203)	(274,894)	(4,438,291)
Purchase of patents		(330,000)	(330,000)
Deposits			(43,856)
Net cash (used in) investing activities	(3,042,203)	(604,894)	(4,812,147)
Cash flows from financing activities:			
Proceeds from related party notes payable and debentures			2,593,000
Proceeds from sale of common stock	68,442,553	121,861	135,531,783
Costs related to sale of common stock	(4,999,777)		(9,654,687)

Proceeds from sale of Luoxis common stock (Note 3)		3,465,000	4,652,500
Costs related to sale of Luoxis common stock (Note 3)		(530,960)	(672,210)
Proceeds from common stock subscribed			177,003
Proceeds from sales of Series A Preferred Stock			1,115,020
Advances (to) from shareholders			(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	63,442,776	3,055,901	133,503,437
Net change in cash and cash equivalents	51,916,305	(1,155,168)	78,225,754
Cash and cash equivalents at beginning of period	26,309,449	17,682,517	
Cash and cash equivalents at end of period	$ 78,225,754	$ 16,527,349	$ 78,225,754
Supplementary cash flow information:			
Interest paid	$	$	$ 29,317
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	$	$ 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	$	$ 226,298	$ 313,064
Merger liability - shares exchanged for options	$	$	$ 574,000
Debenture warrant exercise fair value adjustment	$	$ 8,497	$ 1,551,175

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

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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), Vyrix Pharmaceuticals, Inc. (Vyrix) and Luoxis Diagnostics, Inc. (Luoxis), a 80.9% owned subsidiary see Note 3. 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, 2013, 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 March 31, 2014 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 March 31, 2014 is unaudited.

We are a development stage biopharmaceutical company focused on primarily developing compounds that decrease inflammation by (i) inhibiting specific pro-inflammatory compounds by affecting specific pathways at the protein expression and at the transcription level; (ii) activating specific phosphatase or depleting available phosphate needed for the inflammation process; and (iii) decreasing vascular permeability. We are also focused on monetizing our sexual dysfunction portfolio and diagnostic platform.

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 s 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.

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Note 2 Fixed Assets

Fixed assets are recorded at cost and are depreciated on the straight-line method over estimated useful lives, generally five years. Fixed assets consist of the following:

	As of March 31, 2014	As of December 31, 2013
Manufacturing Facility/Clean Room - in progress	$ 3,989,043	$ 1,000,843
Office furniture and equipment	150,807	116,088
Lab equipment	298,440	279,157
Less accumulated depreciation	(121,103)	(97,584)
Fixed assets, net	$ 4,317,188	$ 1,298,504

Note 3 Formation of Subsidiaries

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 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 were exercisable one year thereafter. Concurrent with the March 15, 2013 closing, $330,000 was paid to Trauma Research LLC (TRLLC) and 50,000 shares of Luoxis common stock valued at $50,000 were 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. As a result of the private placement closings, Ampio owns 80.9% of Luoxis. The consolidated financial statements include Luoxis since Ampio has a controlling financial interest and the third-party holdings (19.1%) are referred to as non-controlling interests .

On November 18, 2013, Ampio formed Vyrix Pharmaceuticals, Inc., a wholly-owned subsidiary, to provide a platform to focus and monetize its sexual dysfunction portfolio.

Note 4 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 5 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 warrants associated with the derivative liability expired on December 31, 2013, however, all the warrants were exercised prior to expiration. During the first quarter of 2013, a charge of $126,478 resulted from the change in fair value of these derivative financial instruments.

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Note 6 Commitments and Contingencies

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

	Total	2014	2015	2016	2017	2018	Thereafter
Manufacturing Facility/Clean Room - in progress	$ 5,257,210	$ 5,257,210	$	$	$	$	$
Ampion supply agreement	11,475,000	1,275,000	2,550,000	2,550,000	2,550,000	2,550,000	
Clinical research and trial obligations	8,257,652	8,257,652					
Sponsored research agreement with related party	1,625,000	243,750	325,000	325,000	325,000	325,000	81,250
Office lease	3,321,113	180,613	216,836	296,639	306,312	315,985	2,004,729
Employment agreements	1,172,083	594,583	411,250	166,250			
	$ 31,108,059	$ 15,808,808	$ 3,503,086	$ 3,337,889	$ 3,181,312	$ 3,190,985	$ 2,085,979

Manufacturing Facility/Clean Room In Progress

The manufacturing facility/clean room will provide commercial scale, FDA compliant, GMP manufacturing of Ampion, an advanced research and development laboratory as well as a sufficient office space to consolidate all operations of the Company in a single facility. The Company continues to enter into contracts for the construction of the facility as well as specialized equipment.

Ampion Supply Agreement

In connection with the manufacturing facility/clean room, in October 2013, Ampio entered into a human serum albumin ingredient and purchase sale agreement with a total commitment of $11,475,000.

Clinical Research Obligations

In connection with upcoming clinical trials, Ampio has a remaining commitment of $2,709,623 on contracts related to the Ampion study drug and $5,548,029 remaining contract commitments related to the Optina study drug.

Sponsored Research Agreement with Related Party

Ampio entered into a Sponsored Research Agreement with TRLLC, 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. As further noted

in Note 9 Related Party Transactions, in March 2014, the Sponsored Research Agreement was extended through March 2019, including a no termination period through March 2017. In a subsequent Addendum, the parties also agreed to increase the equivalent value of the personnel provided by Ampio from $263,750 to $325,000 per year.

Leases

On May 20, 2011, Ampio entered into a non-cancellable operating lease for office space effective June 1, 2011, which expires July 2014. Commitments include the annual operating expense increase for 2014. On December 13, 2013, Ampio entered into a 125 month non-cancellable operating lease for new office space and the manufacturing facility effective May 1, 2014. The new lease has an initial base rent of $23,376 per month, with the total base rent over the term of the lease of approximately $3.3 million. Rent expense for the respective periods follows:

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013
Rent expense	$ 29,954	$ 29,560

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Employment Agreements

As of March 31, 2014, Ampio has employment agreements with four of its executive officers and the CEO of Vyrix. Under the employment agreements, the officers are collectively entitled to receive $1,015,000 in total salaries, plus a 50% discretionary performance bonus related to milestone achievements. The employment agreements expire July 31, 2014 with respect to our chief scientific officer and chief regulatory affairs officer, and expire in 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 TRLLC is excluded from the officers employment agreements commitment. Vyrix also has an employment agreement with its chief executive officer. The agreement is for a term of 36 months beginning on November 18, 2013. The chief executive officer is entitled to receive $210,000 in annual salary, plus a 50% discretionary performance bonus and 500,000 Vyrix stock options with 25% vesting upon grant and 25% annual vesting over three years.

Note 7 Common Stock

Capital Stock

At March 31, 2014 and December 31, 2013, 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. The registration statement also registered 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 December 26, 2013, Ampio filed an additional 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 $100 million for offering from time to time in the future, as well as 1.5 million shares of common stock available for sale by selling shareholders. The shelf registration was declared effective on January 22, 2014 by the Securities and Exchange Commission.

As a result of the equity raises subsequent to September 30, 2011, $60 million remains under the Form S-3 filed on December 26, 2013.

Underwritten Public Offerings

On March 5, 2014, Ampio completed an underwritten public offering for the sale of 9,775,000 shares of common stock at a price of $7.00 per share. Gross proceeds to the Company were $68,425,000 with net proceeds of $63,425,223 after underwriter fees and cash offering expenses.

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 Placement

On September 30, 2013, Ampio closed on the sale of 4,600,319 shares of common stock at $5.50 per share, for a total of $25,301,754 of gross proceeds and $25,003,986 net proceeds after offering costs. The sale of the common stock was made pursuant to the Form S-3 Shelf Registration.

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.

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, which amount has been included in total offering costs in the statement of change in stockholders equity (deficit).

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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 11,700,000 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 three months ended March 31, 2014 using the following assumptions:

Expected volatility	72% - 83%
Risk free interest rate	1.51% - 2.27%
Expected term (years)	5.0 - 7.0
Dividend yield	0%

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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, 2012	4,922,815	$ 2.25	8.36	$ 7,132,347
Granted	1,120,000	$ 6.54		
Exercised	(333,176)	$ 3.23		
Forfeited/Cancelled	(574,581)	$ 1.89		
Outstanding December 31, 2013	5,135,058	$ 3.54	8.74	$ 10,273,070
Granted	140,000	$ 7.46		
Exercised	(69,504)	$ (0.90)		
Forfeited/Cancelled		$		
Outstanding March 31, 2014	5,205,554	$ 3.69	8.67	$ 10,953,069
Exercisable at March 31, 2014	4,692,661	$ 2.55	6.78	$ 5,462,707
Available for grant at March 31, 2014	5,174,559			

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. During the first quarter of 2014, Luoxis granted 150,000 options to officers and consultants. The options have an exercise price of $1.00 and the same vesting schedule as those granted on June 15, 2013. The fair value of these options totaling $101,242 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	79.41% - 81.93%
Risk free interest rate	0.75% - 1.38%
Expected term (years)	5.0 - 6.5
Dividend yield	0%

Luoxis stock option activity is as follows:

	Number of Options	Exercise Price	Weighted Average Remaining	Aggregate Fair Value

				Contractual Life	
Granted June 15, 2013	1,800,000	$	1.00		
Outstanding December 31, 2013	1,800,000	$	1.00	9.72	$ 1,272,366
Granted	150,000	$	1.00		
Exercised		$			
Forfeited/Cancelled		$			
Outstanding March 31, 2014	1,950,000	$	1.00	9.27	$ 1,373,607
Exercisable at March 31, 2014	487,500	$	1.00	9.27	$ 327,712
Available for grant at March 31, 2014	3,050,000				

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Vyrix has also adopted a 2013 Stock Option Plan (the Vyrix 2013 Plan) which reserved 5,000,000 shares of its common stock for issuance to officers, employees and consultants. As of March 31, 2014, 950,000 shares had been granted to a director, officers and consultants. Twenty-five percent or 237,500 shares vested immediately and the remainder vest annually over three years. On November 18, 2013, 500,000 of these shares were granted to the Vyrix Chief Executive Officer and the exercise price was to be based upon a future private equity offering. Management estimated a price of $1.75 per common share for valuing the option grant. The grant was valued utilizing the Black-Scholes option pricing model using the same methodology as described above for Ampio. The valuation resulted in a charge of $140,070 in the fourth quarter of 2013. In the first quarter of 2014, Vyrix engaged an independent third party consulting firm to perform a valuation which was completed and the stock price was set at $0.70 per share. All 950,000 options have been revalued utilizing the $0.70 per share. As a result of the previous charge in the fourth quarter of 2013 and the revision of the exercise price, a reduction of stock compensation expense of $84,041 is reflected in the first quarter of 2014. Assumptions are as follows:

Expected volatility	62.81% - 76.42%
Risk free interest rate	0.90% - 2.02%
Expected term (years)	5.0 - 6.5
Dividend yield	0%

Vyrix stock option activity is as follows:

	Number of Options	Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Fair Value
Granted November 18, 2013	500,000	$ 1.75		
Outstanding December 31, 2013	500,000	$ 1.75	9.94	$ 557,134
Granted	450,000	$ 0.70		
Exercised		$		
Forfeited/Cancelled		$		
Outstanding March 31, 2014	950,000	$ 0.70	9.78	$ 416,369
Exercisable at March 31, 2014	237,500	$ 1.00	9.78	$ 90,388
Available for grant at March 31, 2014	4,050,000			

Stock-based compensation expense related to the fair value of stock options was included in the consolidated statements 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.

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The following table summarizes stock-based compensation expense for the three months ended March 31, 2014 and 2013:

	Three Months Ended March 31,	
	2014	2013
Research and development expenses		
Stock options		
Ampio	$ 638,432	$ 154,691
Luoxis	$ 51,584	$
Vyrix	$ 29,151	$
General and administrative expenses		
Common stock issued for services	30,000	88,050
Stock options		
Ampio	299,007	443,788
Luoxis	58,015	
Vyrix	(54,958)	
	$ 1,051,231	$ 686,529
Unrecognized expense at March 31, 2014		
Ampio	$ 3,607,789	
Luoxis	$ 785,585	
Vyrix	$ 302,381	
Weighted average remaining years to vest		
Ampio	1.38	
Luoxis	2.26	
Vyrix	2.79	

Warrants

Ampio issued warrants in conjunction with its Senior Convertible Debentures, 2011 Private Placements and an underwritten public offering. A summary of all Ampio warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding December 31, 2012	754,371	$ 3.00	3.01
Warrants exercised - Debenture holders	(160,679)	$ (1.75)	
Warrants exercised - Private/Registered Direct Placements	(4,504)	$ (3.13)	
Warrants exercised - Private/Registered Direct Placements	(61,498)	$ (4.06)	
Outstanding December 31, 2013	527,690	$ 2.93	2.44

Warrants exercised - Private/Registered Direct Placements	(11,261)	$	(3.13)	
Warrants exercised - Private/Registered Direct Placements	(100)	$	(4.06)	
Outstanding March 31, 2014	516,329	$	3.26	2.19

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

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 4.17 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

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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/Life Sciences has a sponsored research agreement with TRLLC, an entity controlled by our director and Chief Scientific Officer, Dr. Bar-Or. Under the terms of the research agreement, Ampio is to provide personnel and equipment with an equivalent value of $263,750 per year and to make monthly equipment lease payments of $7,236 on behalf of TRLLC. Lease commitments expired as of January 2011. In exchange, TRLLC will assign any intellectual property rights it develops on our behalf under the research agreement. The research agreement expires on August 31, 2014 and may be terminated by either party on six months notice or immediately if either party determines that the other is not fulfilling its obligations under the agreement.

On March 17, 2014, Ampio, Luoxis and TRLLC entered into an Addendum to the research agreement to extend the termination date through March 31, 2019, including a no termination period through March 31, 2017, and to significantly modify and expand the research activities for Ampio and Luoxis in support of their business plans. In exchange for TRLLC extending the terms of the research agreement and for the expanded services, Ampio and Luoxis agreed to prepay TRLLC in the aggregate amounts of $725,000 and $615,000, respectively, during 2014. A total of $740,000 was paid in the first quarter of 2014 and the remaining balance is due as follows: $150,000, $300,000 and $150,000 in 2014 quarters two, three and four, respectively. The total prepaid of $1,340,000 is being amortized over the contract term of 60.5 months and is split between current and long-term on the balance sheet. In a subsequent addendum, the parties also agreed to increase the equivalent value of the personnel provided by Ampio from $263,750 to $325,000 per year.

In June 2013, Luoxis entered into an agreement with 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. In September 2013, Luoxis entered into an addendum to the agreement which provides for Luoxis to pay an additional $2,000 per month. These agreements are cancellable upon thirty day notice.

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 3, the intellectual property associated with the license agreements was assigned to Luoxis.

Immediately prior to the 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 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.

Note 10 Litigation

On August 30, 2013, Ampio was notified of a civil complaint filed against the Company and certain of its directors and executive officers as defendants. The Complaint alleges that the defendants breached a contract with the plaintiffs for consulting services the plaintiffs purportedly provided during two time periods: between November 2009 and February 2010 in connection with a proposed reverse merger transaction, and between mid-2010 and 2012. The plaintiffs seek an unspecified amount of compensatory damages and other relief, including 930,000 shares of the Company s common stock, and also assert claims for promissory estoppel, unjust enrichment and fraudulent inducement and concealment. The Company believes these claims are without merit and intends to defend this lawsuit vigorously. We believe the likelihood of a loss contingency related to this matter is remote and, therefore, no provision for a loss contingency is required.

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Note 11 Subsequent Events

On April 9, 2014, Vyrix entered into a Distribution and License Agreement (the Paladin Agreement) with Endo Ventures Limited, which recently acquired Paladin Labs, Inc. (Paladin), whereby Paladin has exclusive rights to market, sell and distribute Zertane in Canada, the Republic of South Africa, certain countries in Sub-Saharan Africa, Colombia and Latin America. The Paladin Agreement expires on a country by country basis on the latter of fifteen years after the first commercial sale of the product in that country or expiration of market exclusivity for Zertane in that country. Paladin paid $250,000 to Vyrix upon signing the Paladin Agreement and may make milestone payments aggregating up to $3,025,000 based upon achieving Canadian and South African product regulatory approval and achieving specific sales goals. In addition, the Paladin Agreement provides that Paladin pay royalties based on sales volumes.

On April 16, 2014, Vyrix filed a Form S-1 with the Securities and Exchange Commission relating to a proposed initial public offering of Vyrix common stock.

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 consolidated financial statements. 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 February 14, 2014.

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 primarily developing compounds that decrease inflammation by (i) inhibiting specific pro-inflammatory compounds by affecting specific pathways at the protein expression and at the transcription level; (ii) activating specific phosphatase or depleting available phosphate needed for the inflammation process; and (iii) decreasing vascular permeability. We are also focused on monetizing our sexual dysfunction portfolio and diagnostic platform.

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, BioScience s 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

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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. The exercise price of the warrants associated with the Senior Convertible Debentures was fixed at $1.75 per share and the warrants expired on December 31, 2013. All of the warrants were exercised prior to expiration.

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.

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.

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.

In September 2013, we completed a registered direct placement offering for the sale of 4,600,319 shares of common stock at a price of $5.50 per share. Our net proceeds from this offering, after deducting our estimated offering expenses, was $25.0 million.

In November 2013, we formed a subsidiary, Vyrix Pharmaceuticals, Inc. (Vyrix) to focus on obtaining FDA approval and commercialization of our premature ejaculation product, Zertane, and to further develop our combination product, Zertane ED. Vyrix filed a Form S-1 on April 16, 2014 to launch an Initial Public Offering to raise capital for filing an IND, conducting clinical trials and obtaining FDA approval.

On March 5, 2014, we completed an underwritten public offering for the sale of 9,775,000 shares of common stock at a price of $7.00 per share. Gross proceeds were $68,425,000 with net proceeds of $63,425,223 after underwriter fees and cash offering expenses.

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We currently have a Form S-3 on file with the Securities and Exchange Commission that has $60 million remaining to register Ampio common stock and warrants. The Form S-3 was declared effective on January 22, 2014.

Product Update

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

AMPION for Osteoarthritis of the Knee (OAK)

SPRING Study

On April 9, 2014, we announced that the results of the 20 week extension of the Ampion SPRING study would be presented by Dr. Nathan Wei, MD of The Arthritis Treatment Center in Frederick, MD at the Western Orthopedic Association Conference in July 2014. This 20-week extension of a multicenter, randomized, vehicle-controlled, double-blind study evaluated the safety and efficacy of a single intra-articular injection of Ampion treatment of inflammation-associated pain in symptomatic OAK. A summary of the results follows:

Ninety-seven patients who received a 4 mL intra-articular injection of Ampion or vehicle control were followed for an additional 8 weeks beyond the initial 12-week endpoint of the SPRING study. Efficacy measures included changes from baseline in Western Ontario and McMaster Universities Osteoarthritis (WOMAC) pain and function subscores. Patients were considered responders if they achieved ³40% improvement in WOMAC pain and function.

In a subgroup of patients with moderate-to-severe OAK (Kellgren-Lawrence grades 3-4; n=64), there were statistically significant improvements in WOMAC pain (mean change from baseline -0.99 vs -0.65) (p=0.005) and function scores (-0.85 vs -0.58) (p=0.04) over 20 weeks for patients who received Ampion compared with vehicle control, respectively.

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At 20 weeks, the percentage of patients in the moderate-to-severe subgroup who reported a reduction in pain was significantly higher for patients who received Ampion (50%) compared to those who received vehicle control (25%) (p=0.04).

Similar rates and severity of adverse events were observed in the Ampion and vehicle control groups. A single injection of Ampion was associated with sustained improvements in knee pain over 20 weeks. (p=0.005)

Ongoing STEP Pivotal Trial.

On January 13, 2014, we announced the first patient injection in the phase III pivotal clinical trial of Ampion for the acute treatment of OAK. The Phase III STEP study has been designed to enroll 500 patients and the primary endpoint is reduction in pain for the patients treated with Ampion compared to saline placebo control at 12 weeks. STEP is a randomized, placebo-controlled, double-blind study in which patients with osteoarthritis knee pain will be randomized to receive either a 4 mL single injection of Ampion or saline placebo control. The clinical effects of acute treatment on osteoarthritic pain will be evaluated during clinic visits at 6, 12, and 20 weeks using WOMAC osteoarthritis Index and the Patient s Global Assessment (PGA) of disease severity. Safety will be assessed by recording adverse events, concomitant medications, physical examination, vital signs and clinical laboratory tests. On February 18, 2014, we announced the completion of enrollment and dosing of 500 patients. Topline results are anticipated in the third quarter of 2014 and we expect to file the Biologic License Application (BLA) later this year.

Ampion Manufacturing Facility

On December 16, 2013, we announced a ten-year lease of a multi-purpose facility located in the Denver metropolitan area. Renovation began in January 2014 and will provide commercial scale, FDA compliant, state-of-the-art, cGMP manufacturing of Ampion, an advanced research and development laboratory as well as a sufficient office space to consolidate all operations of the Company in a single facility. Total cost of the facility is estimated to be $10 million. Our new manufacturing facility will initially provide registration batches of Ampion supporting the BLA. Once the manufacturing operation is approved by the FDA for commercial production, the facility is expected to have an annual production capacity of approximately ten million doses of Ampion. More than 50% of the raw material, HSA, required to meet this capacity has already been secured through a long-term, non-exclusive, supply agreement. We anticipate that the new facility will be fully operational by summer 2014.

Future Development

We also intend to study Ampion for therapeutic applications outside of osteoarthritis of the knee. We expect to engage development partners to study Ampion in various conditions including: (i) acute and chronic inflammatory conditions; (ii) degenerative bone disease; and (iii) respiratory and allergic disorders. Based on the continuing evaluation, we are also studying Ampion s effects on cellular behavior to indicate potential effects on disease modification across multiple conditions. If successful, we believe these additional formulations and potential therapeutic indications will supplement the Ampion clinical portfolio, and will enable clinical applications in large therapeutic markets where there are significant unmet needs. Specifically, we were planning pilot trials in Australia for (1) multiple injections for OAK to evaluate cartilage formations, (2) Crohn s disease and (3) Chronic Obstructive Pulmonary Disease (COPD), however, we have recently decided to move those trials to the United States for the purpose of surrogate endpoint development in accordance with FDA processes.

OPTINA for Diabetic Macula Edema

Our Optina trials are continuing and we have enrolled 346 patients, or 77%, out of the 450 required to complete the trial.

SUBSIDIARIES

Luoxis Diagnostics, Inc.

On April 2, 2014, Luoxis announced that it had obtained CE Marking in Europe for its RedoxSYS Diagnostic System, a blood-based platform for assessing the level of oxidative stress in the body. This regulatory clearance allows Luoxis to engage in strategic market development activities designed to establish the clinical utility of the RedoxSys system in the critical care setting and position Luoxis for a launch in Europe, which is currently anticipated for 2015. Luoxis also announced on April 22, 2014, that it obtained Health Canada Class II Medical Device approval for its RedoxSYS Diagnostic System which will allow development of the Canadian market.

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Vyrix Pharmaceuticals, Inc.

On April 9, 2014, Vyrix entered into a Distribution and License Agreement (the Paladin Agreement) with Endo Ventures Limited, which recently acquired Paladin Labs Inc. (Paladin), whereby Paladin has exclusive rights to market, sell and distribute Zertane in Canada, the Republic of South Africa, certain countries in Sub Saharan Africa, Colombia and Latin America. The Paladin Agreement expires on a country by country basis the latter of fifteen years after the first commercial sale of the product in that country or expiration of market exclusivity for Zertane in that country. Paladin paid $250,000 to Vyrix upon signing the Paladin Agreement and may make milestone aggregating up to $3,025,000 based upon achieving Canadian and South African product regulatory approval and achieving specific sales goals. In addition, the Paladin Agreement provides that Paladin pay royalties based on sales volume.

Known Trends or Future Events

We have not generated any significant revenues and have therefore incurred significant net losses totaling $74.5 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 $63.4 million, $29 million, $15.4 million and $19.4 million through the sale of common stock in the first quarter of 2014 and the years, 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 and commercialization of Ampion and Optina. We also intend to limit the extent of these losses by entering into co-development, licensing or collaboration agreements with one or more strategic partners. We also intend to monetize the men s health products of Vyrix and the ORP diagnostic device of Luoxis, either through sales or initial public offerings. 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 consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of the consolidated 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.

Our significant accounting policies and estimates are included in our 2013 Annual Report reported on Form 10-K, filed with the SEC on February 14, 2014. During the first three months of 2014, there were no significant changes to our significant accounting policies and estimates.

Results of Operations March 31, 2014 Compared to March 31, 2013

Results of operations for the three months ended March 31, 2014 (the 2014 quarter) and the three months ended March 31, 2013 (the 2013 quarter) reflected losses of approximately $10,472,000 and $4,208,000, respectively. These losses include non-cash charges related to derivative expense, stock-based compensation, common stock issued for services and depreciation and amortization in the amount of $1,104,000 in the 2014 quarter and $831,000 in the 2013 quarter.

Revenue

We are a development stage enterprise and have not generated material revenue in our operating history. The $12,500 license revenue recognized in the 2014 quarter and 2013 quarter 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 is being recognized over 10 years.

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Expenses

Research and Development

Research and development costs are summarized as follows:

	Three Months Ended March 31,	
	2014	2013
Labor	$ 399,000	$ 318,000
Patent costs	609,000	462,000
Stock-based compensation	719,000	155,000
Clinical trials and sponsored research	6,623,000	1,684,000
Consultants and Other	64,000	168,000
	$ 8,414,000	$ 2,787,000

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 $5,627,000, or 202%, for the 2014 quarter compared to the 2013 quarter. The increase is 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 Ampio, Luoxis and Vyrix and the continuing vesting of awards granted in previous years.

General and Administrative

General and administrative costs are summarized as follows:

	Three Months Ended March 31,	
	2014	2013
Labor	$ 707,000	$ 216,000
Stock-based compensation	332,000	532,000
Professional fees	446,000	170,000
Occupancy, travel and other	521,000	353,000
Directors fees	67,000	41,000
	$ 2,073,000	$ 1,312,000

General and administrative costs increased $761,000, or 58%, for the 2014 quarter compared to the 2013 quarter. The increase is primarily due to increased professional staffing and occupancy, travel and other. These other expenses also include insurance, listing and filing fees and investor relations.

Net Cash Used in Operating Activities

During the 2014 quarter, our operating activities used approximately $8.5 million in cash which was less than the net loss of $10.5 million primarily as a result of the non-cash stock based compensation and accounts payable offset by prepaid research and development related party.

In the 2013 quarter, the use of cash was $3.6 million which was less than the net loss of $4.2 million principally as a result of non-cash stock-based compensation.

Net Cash Used in Investing Activities

During the 2014 quarter, cash was used to acquire manufacturing machinery and equipment. Fixed assets reflect purchases for Ampio s new manufacturing facility.

Net Cash from Financing Activities

Net cash provided by financing activities in the 2014 quarter reflects gross proceeds from the public offering of $68.4 million with net proceeds of $63.4 million.

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In the 2013 quarter, net cash provided by financing activities of $3.1 million reflects the proceeds from the Luoxis private financing of $2.9 million and $0.1 million from the exercise of stock options.

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 March 31, 2014, we had cash and cash equivalents totaling $78.2 million and $4.4 million in accounts payable. Based upon our current expectations, we believe our capital resources at March 31, 2014 will be sufficient to fund our currently planned operations into the first half of 2016. 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 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. Vyrix has also filed a Form S-1 to raise capital for advancing its lead product, Zertane, however, there can be no assurance that this capital raise will be successful or adequate to fund the commercialization of Zertane.

We have prepared a budget for 2014 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 $700,000 and $900,000 per month. The cash we raised in March 2014 will be used for working capital and general corporate purposes including continuation and completion of our Ampion and Optina clinical trials, submission of a BLA relating to Ampion, a NDA relating to Optina, the build out of our new office and manufacturing facility, acquisition of manufacturing equipment, and the potential hiring of manufacturing personnel. The total of these expenditures is estimated to be in the range of $25 million to $28 million. As additional funding is required, 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.

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.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

On August 30, 2013, Ampio became aware of a civil complaint filed in the District Court for Arapahoe County, Colorado on or about August 28, 2013 (the Complaint). The Complaint names the Company and certain of its directors and executive officers as defendants. The Complaint alleges that the defendants breached a contract with the plaintiffs for consulting services the plaintiffs purportedly provided during two time periods: between November 2009 and February 2010 in connection with a proposed reverse merger transaction, and between mid-2010 and 2012. The plaintiffs seek an unspecified amount of compensatory damages and other relief, including 930,000 shares of the Company s common stock, and also assert claims for promissory estoppel, unjust enrichment and fraudulent inducement and concealment. The Company believes these claims are without merit and intends to defend this lawsuit vigorously.

The Company is currently not party to any other 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, adverse 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 February 14, 2014. However, the Company will continue to require additional capital, the receipt of which is not assured. Also, the Company is currently developing and building its own manufacturing facility which will manufacture Ampion for registration, batching and future clinical supply as well as commercial supply. If we experience delays or difficulties in this effort, including the FDA requiring us to conduct a comparability study evaluating the product that we used for clinical studies involving Ampion with the product that we intend to market in the United States, which will be manufactured at our facility in the Denver metropolitan area, the Company s development and commercialization efforts may be delayed and its costs may increase.

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.

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Item 6. Exhibits

Exhibit Number	Description
10.1	Underwriting Agreement, dated February 27, 2014, by and among Citigroup Global Markets Inc., Jefferies LLC and Ampio Pharmaceuticals, Inc. (1)
10.2**	Addendum No. 4, dated March 17, 2014, to the Sponsored Research Agreement, dated September 1, 2009, by and among Trauma Research LLC, Luoxis Diagnostics, Inc. and Ampio Pharmaceuticals, Inc.***
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	XBRL (eXtensible Business Reporting Language). The following materials from Ampio Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 formatted in XBRL: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Stockholders Equity (Deficit), (iv) the Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements.

(1) Incorporated by reference from Registrant s Form 8-K filed February 28, 2014.

* 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.

** Filed herewith.

*** Confidential portions of this exhibit have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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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: May 7, 2014

By: /s/ Mark D. McGregor
Mark D. McGregor
Chief Financial Officer
Date: May 7, 2014