

Ampio Pharmaceuticals, Inc.  
Form 10-Q  
November 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: September 30, 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**  
**(State or other jurisdiction of**  
**incorporation or organization)**  
**373 Inverness Parkway, Suite 200**  
**Englewood, Colorado 80112**  
**(Address of principal executive offices, including zip code)**  
**(720) 437-6500**  
**(Registrant's telephone number, including area code)**

**26-0179592**  
**(IRS Employer**  
**Identification No.)**

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 November 1, 2014, there were 51,972,266 shares outstanding of Common Stock, par value \$0.0001, of the registrant.

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**AND SUBSIDIARIES**  
**FOR THE QUARTER ENDED SEPTEMBER 30, 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 clinical trials for our product candidates, 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;*

*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; and*

*progress of our manufacturing facility/clean room.*

*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; and*

*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.*

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Consolidated Financial Statements****AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES****Consolidated Balance Sheets**

	September 30, 2014 (Unaudited)	December 31, 2013
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 56,830,455	\$ 26,309,449
Accounts receivable	722,163	
Prepaid expenses	383,175	131,986
Prepaid research and development - related party (Note 9)	265,786	
<b>Total current assets</b>	<b>58,201,579</b>	<b>26,441,435</b>
Fixed assets, net (Note 2)	9,805,280	1,298,504
In-process research and development	7,500,000	7,500,000
Patents, net	681,866	734,957
Long-term portion of prepaid research and development - related party (Note 9)	930,247	
Deposits	33,856	43,856
	18,951,249	9,577,317
<b>Total assets</b>	<b>\$ 77,152,828</b>	<b>\$ 36,018,752</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities		
Accounts payable	\$ 2,844,632	\$ 1,900,576
Accrued liabilities - related party (Note 9)	150,000	
Accrued bonuses		522,056
Deferred rent	56,839	
Deferred revenue	85,716	50,000
<b>Total current liabilities</b>	<b>3,137,187</b>	<b>2,472,632</b>
Long-term deferred revenue	490,176	331,250
Long-term deferred rent	642,777	
<b>Total liabilities</b>	<b>4,270,140</b>	<b>2,803,882</b>
Commitments and contingencies (Note 6)		

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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 - 51,972,266 in 2014 and 42,065,031 in 2013	5,197	4,207
Additional paid-in capital	165,379,799	96,942,744
Advances to stockholders	(90,640)	(90,640)
Accumulated Deficit	(91,992,888)	(63,779,155)
Total Ampio stockholders equity	73,301,468	33,077,156
Non-controlling interests	(418,780)	137,714
Total equity	72,882,688	33,214,870
Total liabilities and equity	\$ 77,152,828	\$ 36,018,752

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

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

	Three Months Ended September 30, 2014		Nine Months Ended September 30, 2013	
	2014	2013	2014	2013
License revenue	\$ 21,429	\$ 12,500	\$ 55,358	\$ 37,500
Expenses				
Research and development	6,153,152	4,419,703	19,562,123	11,481,871
Research and development - related party (Note 9)	66,446		143,967	
General and administrative	3,299,043	1,536,231	9,261,938	5,042,227
Total operating expenses	9,518,641	5,955,934	28,968,028	16,524,098
Other income (expense)				
Interest income	5,547	1,114	16,547	8,563
Derivative expense		(251,610)		(517,477)
Total other income (expense)	5,547	(250,496)	16,547	(508,914)
Net loss	(9,491,665)	(6,193,930)	(28,896,123)	(16,995,512)
Net loss applicable to non-controlling interests	211,635	121,851	682,390	327,184
Net loss applicable to Ampio	\$ (9,280,030)	\$ (6,072,079)	\$ (28,213,733)	\$ (16,668,328)
Weighted average number of Ampio common shares outstanding	51,969,836	37,106,190	49,638,257	37,090,019
Basic and diluted Ampio net loss per common share	\$ (0.18)	\$ (0.16)	\$ (0.57)	\$ (0.45)

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



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

	Series A Preferred Stock Shares	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Advances to Stockholders	Accumulated Deficit	Non-controlling Interests	Total Stockholders Equity
Balance - December 31, 2013		42,065,031	\$ 4,207	\$ 96,942,744	\$ (90,640)	\$ (63,779,155)	\$ 137,714	\$ 33,214,870
Issuance of common stock for services (unaudited)		4,209		30,000				30,000
Issuance of common stock in exchange for cash in March 2014, net of offering costs of \$4,999,777 (unaudited)		9,775,000	978	63,424,244				63,425,222
Non-controlling interests on contributed assets (unaudited)				(125,896)			125,896	
Options exercised, net (unaudited)		120,519	12	(15,480)				(15,468)
Warrants exercised, net (unaudited)		7,507						
Stock-based compensation (unaudited)				5,124,187				5,124,187
Net loss (unaudited)						(28,213,733)	(682,390)	(28,896,123)
Balance - September 30, 2014 (unaudited)		51,972,266	\$ 5,197	\$ 165,379,799	\$ (90,640)	\$ (91,992,888)	\$ (418,780)	\$ 72,882,688

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



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

	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
<b>Cash flows from operating activities:</b>		
Net loss	\$ (28,896,123)	\$ (16,995,512)
Depreciation and amortization	209,837	97,319
Loss on disposal of fixed assets	28,685	
Amortization of prepaid research and development - related party (Note 9)	143,967	
Common stock issued for services	30,000	88,050
Stock-based compensation expense	5,124,187	2,222,643
Derivative expense		517,477
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
(Increase) in accounts receivable	(722,163)	
(Increase) decrease in prepaid expenses	(251,189)	13,711
(Increase) in prepaid research and development - related party (Note 9)	(1,340,000)	
Decrease in deposits	10,000	
Increase (decrease) in accounts payable	174,662	(34,247)
Increase in accrued liabilities - related party (Note 9)	150,000	
Increase in deferred rent	699,616	
Increase (decrease) in deferred revenue	194,642	(37,500)
(Decrease) in accrued bonuses	(522,056)	
<b>Net cash used in operating activities</b>	<b>(24,965,935)</b>	<b>(14,128,059)</b>
<b>Cash flows used in investing activities:</b>		
Purchase of fixed assets	(7,925,198)	(283,814)
Proceeds from sale of fixed assets	2,385	
Purchase of patents		(330,000)
<b>Net cash used in investing activities</b>	<b>(7,922,813)</b>	<b>(613,814)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of common stock	68,409,531	25,447,318
Costs related to sale of common stock	(4,999,777)	(297,768)
Proceeds from sale of Luoxis common stock (Note 3)		4,652,500
Costs related to sale of Luoxis common stock (Note 3)		(672,210)

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Net cash provided by financing activities	63,409,754	29,129,840
Net change in cash and cash equivalents	30,521,006	14,387,967
Cash and cash equivalents at beginning of period	26,309,449	17,682,517
Cash and cash equivalents at end of period	\$ 56,830,455	\$ 32,070,484
Non-cash transactions:		
Issuance of Luoxis stock for patents	\$	\$ 50,000
Warrant compensation from Luoxis common stock offering costs	\$	\$ 313,064
Debenture warrant exercise fair value adjustment	\$	\$ 33,934
Fixed assets included in accounts payable	\$ 769,394	\$

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

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**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements**

**(unaudited)**

**Note 1 Basis of Presentation, Business and Mergers**

**Basis of Presentation**

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 ), Vyrrix Pharmaceuticals, Inc. ( Vyrrix ) 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 subsidiaries on a consolidated basis and the consolidated results of operations and cash flows for the interim periods presented. The results of operations for the period ended September 30, 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 September 30, 2014 is unaudited. Ampio s activities, being primarily research and development and raising capital, have not generated significant revenue to date.

**Newly Issued Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ( FASB ) issued ASU 2014-09 regarding ASC Topic 606, Revenue from Contracts with Customers . The standard provides principles for recognizing revenue for the transfer of promised goods or services to customers with the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance will be effective for our fiscal year beginning January 1, 2017. Early adoption is not permitted. We are currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

In June 2014, the FASB issued ASU 2014-10, Development Stage Entities (Topic 915) . The guidance eliminates the definition of a development stage entity thereby removing the incremental financial reporting requirements from U.S. GAAP for development stage entities, primarily presentation of inception to date financial statements. The provisions of the amendments are effective for Ampio s calendar year 2015; however, early adoption is permitted and, accordingly, we have elected to implement the guidance in our second quarter 2014 financial statements.

In August 2014, the FASB issued Accounting Standards Update ( ASU ) No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern ( ASU 2014-15 ). ASU 2014-15 is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures. The amendments in this ASU are effective for reporting periods beginning after December 15, 2016, with early adoption permitted. Management is currently assessing the impact the adoption of ASU 2014-15 will have on our Condensed Financial Statements.

**Business**

We are a 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.

## **Mergers**

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.

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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).

**Error in Classification**

Patent costs were previously classified as research and development, however, it was determined that these costs were incorrectly classified and, therefore, have been reclassified as general and administrative expense for all periods presented. Patent costs consist of legal and filing fees related to obtaining and maintaining patents and should have been excluded from research and development activities as set forth in the FASB's Accounting Standards Codification Topic 730, Research and Development. The impact of the correction of this error in classification decreased research and development expenses and correspondingly increased general and administrative expenses for the three months ended September 30, 2014 and 2013 by \$555,000 and \$384,000, respectively, and for the nine months ended September 30, 2014 and 2013 by \$1,827,000 and \$1,358,000, respectively. The correction of this error had no impact on our total operating expenses or our net loss for any periods presented.

**Accounts Receivable**

Accounts receivable for the period ended September 30, 2014 results from refunds from vendors, insurance reimbursement from litigation and the final tenant improvement allowance not received as of September 30, 2014.

**Note 2 Fixed Assets**

Fixed assets are recorded at cost and, once placed in service, are depreciated on the straight-line method over the estimated useful lives. Fixed assets consist of the following:

	As of September 30, 2014	As of December 31, 2013
Manufacturing Facility/Clean Room - in progress	\$ 3,925,000	\$ 1,001,000
Leasehold improvements	4,492,000	
Office furniture and equipment	542,000	116,000
Lab equipment	1,054,000	279,000
Less accumulated depreciation and amortization	(208,000)	(97,000)
Fixed assets, net	\$ 9,805,000	\$ 1,299,000

**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 \$4,653,000 of gross proceeds. Net proceeds were \$3,980,000 after placement agent and legal fees. The placement agent also received 465,250 warrants to purchase Luoxis common stock valued at \$313,000 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 the 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 .



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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. 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 which filing was amended on June 19, 2014. The Company continues to explore strategic alternatives with Vyrix but due to market conditions we have decided to delay the potential initial public offering of Vyrix. Based upon the uncertainty of when or if we will be able to complete the initial public offering of Vyrix, the Company has expensed all of the costs that it has incurred related to the preparation of this potential transaction in the quarter ended September 30, 2014.

**Note 4 License Agreement/Revenue Recognition**

During 2011, Ampio entered into a license, development and commercialization agreement with a major Korean pharmaceutical company which was assigned to Vyrix when it was formed in 2013. 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 \$418,000 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 may be earned and recognized contingent upon achievement of regulatory approvals and cumulative net sales targets, which may take several years. In addition, Ampio may 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.

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 later 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. The upfront payment has been deferred and is being recognized as license revenue over a seven year period. In addition, the *Paladin Agreement* provides that Paladin pays royalties based on sales volume.

**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 three and nine months ended September 2013, a charge of \$252,000 and \$517,000 respectively, resulted from the change in fair value of these derivative financial instruments.

**Note 6 Commitments and Contingencies**

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

Total	2015	2016	2017	2018	Thereafter
-------	------	------	------	------	------------

Remaining  
2014

Manufacturing Facility/Clean Room - in progress	\$ 618,000	\$ 618,000	\$	\$	\$	\$	\$
Ampion supply agreement	11,344,000	1,144,000	2,550,000	2,550,000	2,550,000	2,550,000	
Clinical research and trial obligations	9,691,000	6,537,000	3,154,000				
Sponsored research agreement with related party	1,462,000	81,000	325,000	325,000	325,000	325,000	81,000
Facility lease	3,281,000	70,000	287,000	297,000	306,000	316,000	2,005,000
	\$ 26,396,000	\$ 8,450,000	\$ 6,316,000	\$ 3,172,000	\$ 3,181,000	\$ 3,191,000	\$ 2,086,000

***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 sufficient office space to consolidate the core operations of the Company in a single facility.

***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. As of September 30, 2014, Ampio has received \$131,000 of this human serum albumin.

**Table of Contents*****Clinical Research and Trial Obligations***

In connection with upcoming clinical trials, as of September 30, 2014, Ampio has a remaining commitment of \$5,636,000 on contracts related to the Ampion study drug and \$4,055,000 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 days' 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 \$264,000 to \$325,000 per year.

***Facility Leases***

On May 20, 2011, Ampio entered into a non-cancellable operating lease for office space effective June 1, 2011, which expired 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 initial base rent of \$23,000 per month, with the total base rent over the term of the lease of approximately \$3.3 million and includes rent abatements and leasehold incentives. The Company recognizes rental expense of the facility on a straight-line basis over the term of the lease. Differences between the straight-line net expenses on rent payments are classified as liabilities between current deferred rent and long-term deferred rent. Rent expense for the respective periods is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Rent expense	\$ 98,000	\$ 29,000	\$ 221,000	\$ 88,000

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

At September 30, 2014 and December 31, 2013, Ampio had 100.0 million shares of common stock authorized with a par value of \$0.0001 per share and 10.0 million 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 \$80.0 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 \$100.0 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, \$60.0 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 \$63,425,000 after underwriter fees and cash offering expenses.

***Private Placement Luoxis***

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 \$4,653,000 of gross proceeds. Net proceeds were

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\$3,980,000 after placement agent and legal fees. The placement agent also received 465,250 warrants to purchase Luoxis common stock valued at \$313,000 in connection with the closing, which amount has been included in total offering costs in the consolidated statement of changes in stockholders' equity (deficit).

**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 \$25,302,000 of gross proceeds and \$25,004,000 net proceeds after offering costs. The sale of the common stock was made pursuant to the Form S-3 Shelf Registration.

**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 11.7 million 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 calculates its volatility assumption using the actual changes in the market value of our stock. Ampio has estimated a forfeiture rate of 5.9% based upon historical experience; this is an estimate of options granted that are expected to be forfeited or cancelled before becoming fully vested. 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. During the three months ended September 30, 2014, Ampio granted 480,000 options ranging in price from \$6.48 to \$6.89 to employees which represented the fair market value on date of the grants. Also, during the three month ended September 30, 2014, the Company modified options related to a former executive which accelerated vesting of 275,000 options and extended the exercise period from 90 days after termination to August 15, 2015. Ampio has computed the fair value of all options granted during the nine months ended September 30, 2014 using the following assumptions:

Expected volatility	72% - 108%
Risk free interest rate	1.51% - 2.27%
Expected term (years)	5.0 - 7.0
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, 2013	5,135,058	\$ 3.54	8.74	\$ 10,273,000

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Granted	1,050,000	\$	6.87		
Exercised	(157,226)	\$	1.95		
Forfeited/Cancelled	(34,792)	\$	3.42		
Outstanding September 30, 2014	5,993,040	\$	3.86	7.67	\$ 14,783,000
Exercisable at September 30, 2014	4,699,689	\$	3.36	7.33	\$ 9,558,000
Available for grant at September 30, 2014	4,330,979				

Pursuant to the Luoxis 2013 Stock Option Plan (the 2013 Plan ), 5.0 million shares of its common stock were reserved for issuance. 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 \$1,272,000 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 \$101,000 were also calculated using the Black-Scholes option pricing model utilizing the same methodology as described above for Ampio. During the

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third quarter of 2014, Luoxis granted 885,000 options to officers and consultants. The options have an exercise price of \$1.60 and vest at a rate of 25% over the next four years starting on the one year anniversary of the grant date. Luoxis has estimated a forfeiture rate of 5.9% based upon historical experience; this is an estimate of options granted that are expected to be forfeited or cancelled before becoming fully vested. The fair value of these options totaling \$1,168,000 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% -108%
Risk free interest rate	0.75% - 2.09%
Expected term (years)	5.0 - 7.0
Dividend yield	0%

Luoxis stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Fair Value
Outstanding December 31, 2013	1,800,000	\$ 1.00	9.72	\$ 1,272,000
Granted	1,035,000	\$ 1.49		
Exercised		\$		
Forfeited/Cancelled		\$		
Outstanding September 30, 2014	2,835,000	\$ 1.19	9.11	\$ 2,541,000
Exercisable at September 30, 2014	937,500	\$ 1.00	8.74	\$ 661,000
Available for grant at September 30, 2014	2,165,000			

Vyrix has also adopted a 2013 Stock Option Plan (the Vyrix 2013 Plan ) which reserved 5.0 million shares of its common stock for issuance to officers, employees and consultants. As of September 30, 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 \$140,000 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 valued 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 \$84,000 was reflected in the first quarter of 2014. Assumptions are as follows:

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Expected volatility	63% -76%
Risk free interest rate	0.90% - 2.02%
Expected term (years)	5.0 - 6.5
Dividend yield	0%



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Vyrix stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Fair Value
Outstanding December 31, 2013	500,000	\$ 1.75	9.94	\$ 557,000
Granted	450,000	\$ 0.70		
Exercised		\$		
Forfeited/Cancelled		\$		
Outstanding September 30, 2014	950,000	\$ 0.70	9.29	\$ 416,000
Exercisable at September 30, 2014	237,500	\$ 0.70	9.29	\$ 104,000
Available for grant at September 30, 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 and its subsidiaries determined the fair value as of the date of grant using the Black-Scholes option pricing model and expenses the fair value ratably over the vesting period. The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2014 and 2013:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development expenses				
Stock options				
Ampio	\$ 1,724,000	\$ 554,000	\$ 2,761,000	\$ 932,000
Luoxis	82,000	52,000	185,000	254,000
Vyrix	8,000		46,000	
General and administrative expenses				
Common stock issued for services			30,000	88,000
Stock options				
Ampio	572,000	217,000	1,963,000	893,000
Luoxis	93,000	29,000	186,000	144,000
Vyrix	19,000		(17,000)	
	\$ 2,498,000	\$ 852,000	\$ 5,154,000	\$ 2,311,000
Unrecognized expense at September 30, 2014				
Ampio	\$ 3,850,000			
Luoxis	\$ 1,622,000			

Vyrix	\$ 248,000
Weighted average remaining years to vest	
Ampio	1.25
Luoxis	2.75
Vyrix	2.28

**Table of Contents*****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, 2013	527,690	\$ 2.93	2.44
Warrants exercised - Private/Registered Direct Placements	(11,361)	\$ (3.13)	
Outstanding September 30, 2014	516,329	\$ 3.26	1.69

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 \$3.13 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 3.67 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 \$313,000 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%

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**Table of Contents****Note 9 Related Party Transactions**

Ampio entered into a sponsored research agreement with TRLLC, an entity controlled by our director and Chief Scientific Officer, Dr. Bar-Or, on September 1, 2009, which has been amended five times with the last amendment occurring in March of 2014. Under the amended terms of the research agreement, Ampio will provide personnel with an equivalent value of \$325,000 per year. With the most recent amendment, Ampio also agreed to pay a sum of \$725,000 which is being amortized over the contractual term of 60.5 months and is divided between current and long-term on the balance sheet. Of this amount, we owe one final payment of \$150,000 on October 1, 2014. In return, TRLLC will assign any intellectual property rights it develops on our behalf under the research agreement and undertake additional activities to support Ampio's commercial activities and business plan. This agreement is set to expire on March 31, 2019 and cannot be terminated prior to March 31, 2017.

In June 2013, Luoxis also entered into an agreement with TRLLC. The agreement, which was amended in September 2013, provides for Luoxis to pay \$8,000 per month to TRLLC in consideration for services related to research and development of Luoxis' Oxidation Reduction Potential platform. Starting in March of 2014, Luoxis also agreed to pay a sum of \$615,000 which is being amortized over the contractual term of 60.5 months and is divided between current and long-term on the balance sheet; this amount has been paid in full. This agreement has the same termination and expiration as the agreement between Ampio and TRLLC.

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 \$150,000. 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 \$23,000 was repaid. During the three months ended March 31, 2012 an additional repayment of \$37,000 was received. As of September 30, 2014 and 2013 respectively, \$91,000 of advances to stockholders remained outstanding.

**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 plaintiff for consulting services the plaintiff 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 Complaint also asserts claims for promissory estoppel, unjust enrichment and fraudulent inducement and concealment. In July 2014, the plaintiff dismissed all claims against Dr. David Bar-Or with prejudice. In September 2014, following a five-day trial, the jury returned a defense verdict in favor of the Company and Michael Macaluso on all of the claims presented to it, specifically, plaintiff's claims for breach of contract, fraudulent inducement, and fraudulent concealment. The parties are awaiting a post-trial decision from the court on plaintiff's remaining claims for promissory estoppel and unjust enrichment. The Company believes these claims are without merit and intends to continue 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.

**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](http://www.ampiopharma.com). Information on or linked to the Company website is not incorporated by reference into this Quarterly Report on Form 10-Q. Filings with the SEC can also be obtained at the SEC's website, [www.sec.gov](http://www.sec.gov).

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We are a biopharmaceutical company focused primarily on 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 a diagnostic platform.

## **Financing History/Overview**

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 \$4,653,000 in gross proceeds. Net proceeds were \$3,980,000 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 Ampio common stock at a price of \$5.50 per share. Our net proceeds from this offering, after deducting our estimated offering expenses, were \$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 with the Securities and Exchange Commission on April 16, 2014 which was amended on June 19, 2014 to launch an Initial Public Offering to raise capital for filing an Investigational New Drug application, conducting clinical trials and obtaining FDA approval. The Company continues to explore strategic alternatives with Vyrix but due to market conditions we have decided to delay the potential initial public offering of Vyrix. Based upon the uncertainty of when or if we will be able to complete the initial public offering of Vyrix, the Company has expensed all of the costs that it has incurred related to the preparation of this potential transaction in the quarter ended September 30, 2014.

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

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 which was 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 for the treatment of inflammation-associated pain in symptomatic OAK. A summary of the results is as 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 <sup>3</sup>40% 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.

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)

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**Table of Contents****STEP Study**

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 was designed to enroll 500 patients and the primary endpoint was reduction in pain for the patients treated with Ampion compared to saline placebo control at 12 weeks. STEP was a randomized, placebo-controlled, double-blind study in which patients with osteoarthritis knee pain were randomized to receive either a 4 mL single injection of Ampion or saline placebo control. The clinical effects of acute treatment on osteoarthritic pain were 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 was 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.

On August 21, 2014, we announced the discovery by the independent Clinical Research Organization (CRO) that the study drug (both Ampion and the placebo) were, during shipment to the clinical sites, exposed to lower temperatures than permitted by the drug specifications. On August 25, 2014, we announced that the STEP study experienced deviation from protocol in temperature excursions in over 70% of the drug supply for this study, thus, the Company will not be able to use data from this study for the FDA submission except for the safety data. Subsequently, to eliminate the deviation from protocol in temperature excursions, improvements to shipping protocols, containers and temperature sensors were completed and validated.

**Multiple Injection Studies****STRUT Study**

On June 30, 2014, we announced that we have started patient enrollment for the multiple injection study using Ampion for patients with mostly severe or very severe osteoarthritis of the knee. This trial was different from our prior clinical trials as those trials primarily focused on pain reduction using the WOMAC scale, while this study explored the possibility of additional clinical benefits and potential regeneration of cartilage. This study has two phases. Phase I analyzed safety and no placebo was used, all patients received three intra-articular injections of Ampion (4 mL). Phase II will evaluate the efficacy, cartilage formation as well as safety and the patients will be randomized 1:1, Ampion vs. Saline. This second phase has begun since no serious safety issues were reported with the Phase I study. Each patient has committed to 13 total clinical visits over the duration of 52 weeks. High resolution MRI's will be conducted at baseline, week 12, week 20 and week 52 and will be analyzed by specialized radiologist experts in quantifying cartilage formation. At the same time, knee aspiration will be performed and the synovial fluids will be analyzed by proteomic tools and for specific cartilage regeneration and stem cell biomarkers. Each patient will also keep a detailed activity and exercise log so that positive lifestyle changes can be followed. Although we have used the WOMAC scale to evaluate the efficacy of our prior trials, in and of itself the WOMAC scale is a very subjective measure in that it reports only pain in the prior 48 hours. If patients increased their activity levels because Ampion reduced their pain, they could have experienced discomfort as a result of increased activity alone. Thus, Ampion may provide more clinical benefit than reduction of pain and this multiple injection study is designed to explore that possibility.

On August 5, 2014, we announced the one month results of the open label portion of the multiple injections of Ampion into the knees of patients (n=7) with OAK. The WOMAC A pain score improved by 65% from baseline with the multiple injections at one month post injection (WOMAC A mean improved from 2.2 (0.55) to 0.8 (0.62), mean difference 1.43 (0.406), p=0.01) compared to 33% in the SPRING study at the same time point. In addition, the function score WOMAC C compared to baseline improved by 74% at 4 weeks (WOMAC C mean improved from 2.3 (0.55) to 0.6 (0.58), mean difference 1.70 (0.374), p=0.004). The study also includes serial high resolution MRI's at



various time points that will explore whether there are clinical benefits beyond pain relief.

On August 18, 2014, we announced the 6 week results of the open label portion of the multiple injections of Ampion into the knees of patients (n=7) with OAK. The WOMAC A pain score improved by 86 % from baseline in the multiple injections study at 6 weeks following the first injection (WOMAC A mean improved from 2.2 (0.55) at baseline to 0.3 (0.34) at week 6, mean difference 1.9 (0.3), p=0.001) compared to about 40% in the SPRING study at the same time point. In addition, the function score WOMAC C compared to baseline improved by 87 % at week 6 (WOMAC C mean improved from 2.3 (0.55) to 0.3 (0.23), mean difference 2.0 (0.26), p=0.0003). There were no drug related serious adverse events reported during the first 6 weeks of this current trial.

On October 16, 2014, we announced 12 week results from the open label portion of the multiple injection STRUT study including a 95% improvement from baseline to 12 weeks in the WOMAC A pain sub score, an 89% improvement from baseline to 12 weeks in WOMAC B stiffness sub score, a 92% improvement from baseline to 12 weeks in WOMAC C function sub score and a 59% improvement from baseline to week 12 in the Patient Global Assessment (PGA) of Disease Severity. We also announced the completion of enrollment for the Phase II portion (N=40) of the STRUT study.

### **STRIDE Study**

On September 20, 2014 we announced the STRIDE Study, a randomized, placebo-controlled, double-blind study to evaluate the safety and efficacy of three intra-articular injections of Ampion™ (4 mL) administered two weeks apart in adults with pain due to osteoarthritis of the knee. The STRIDE Study is adequately powered (n=320), follows patients for 24 weeks (primary endpoint at 20 weeks), is a multiple injection study and may function as our second pivotal trial for a Biologics License Application.

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### **Biologics License Application (BLA) Update**

On July 30, 2014 we announced a written response from the FDA accepting our plan for production of Ampion™ in our new facility to satisfy the chemistry, manufacturing and controls requirements for our BLA. The Company is currently planning to file the BLA by the end of second quarter of 2015.

### **OPTINA for Diabetic Macula Edema**

On June 25, 2014, it was announced that we informed the FDA of our intent to reduce the patient sample size in the OptimEyes Study for the treatment of Diabetic Macular Edema (oral treatment with Optina ). This trial was intended to enroll 450 patients and was powered at 95%. The present enrollment of over 355 patients provides an adequate power of 88% which the Company believes is more than sufficient for statistical evaluation. By reducing the sample size, we expect data from this study by the end of the fourth quarter 2014.

On August 20, 2014, it was announced that we received analysis of available data (masked and open label) from the OptimEyes Study. The data of the blinded OptimEyes study is still masked , pending the completion of the 12 week period for several patients, but valuable insight can be obtained by looking at the two portions of the study without unmasking the study. It was explained that 55% of patients (n=198) were refractory to anti-VGEF intra-ocular therapy (no longer showing improvement or responding to treatment). Any efficacy could be an invaluable addition to existing therapies particularly in those patients no longer responding to the approved drugs, including anti-VGEF therapy.

On September 20, 2014, we discussed the 505(b)(2) regulatory pathway for Optina. We believe that a 505(b)(2) regulatory pathway may have several advantages including lower risk because of the already existing safety and efficacy information, lower cost of development due to the smaller scope and number of potential studies and increased speed due to fewer studies.

### **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 operations of the Company in a single facility. Total cost of the facility is estimated to be \$10.2 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. On July 22, 2014, Ampio moved into its new headquarters, manufacturing and research facility.

### **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 and (ii) 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 are planning a pilot trial for Crohn's disease.

## **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. On April 22, 2014, Luoxis announced that the Company had signed a long-term research agreement with a global, US-based pharmaceutical company. Through this research agreement the Company will utilize their RedoxSYS oxidation-reduction potential (ORP) diagnostic system to assess the therapeutic effects of several investigational compounds with different target indications. The research agreement provides for Luoxis participation in multiple global studies being conducted by the pharmaceutical company. On August 11, 2014 Luoxis announced that the Company has expanded its academic and pharmaceutical research network to over 25 sites around the world. To date the Company has initiated over 17 scientific and clinical research studies, and Luoxis expects to initiate over 30 additional studies globally by the end of the year. The Company has engaged over 12 academic research centers across North America and 13 sites in Europe including prominent centers in Belgium, England, France, Germany, Greece, and Wales. Further, to date Luoxis has also initiated research collaborations with five pharmaceutical companies in both the US and Europe, through which these companies are utilizing the RedoxSYS platform to perform drug development research on therapeutic candidates known to affect oxidative stress pathways. These studies span a broad range of therapeutic candidates in numerous disease areas. Finally, on

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August 19, 2014 Luoxis announced an upcoming presentation at the 73rd Annual Meeting of the American Academy of Surgical Trauma (AAST) and Clinical Congress of Acute Care Surgery in Philadelphia, Pennsylvania. This meeting was held September 10-13, 2014. The presentation reported results from a recently completed five-year prospective clinical trial conducted using Luoxis' proprietary RedoxSYS oxidation-reduction potential (ORP) diagnostic platform to assess prognosis and outcomes in patients with traumatic brain injury.

## **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 later 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 volume. 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. The Company continues to explore strategic alternatives with Vyrix but due to market conditions we have decided to delay the potential initial public offering of Vyrix. Based upon the uncertainty of when or if we will be able to complete the initial public offering of Vyrix, the Company has expensed all of the costs that it has incurred related to the preparation of this potential transaction in the quarter ended September 30, 2014.

## **Known Trends or Future Events**

We have not generated any significant revenues and have therefore incurred significant net losses 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, \$29.0 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, 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.

### **Newly Issued Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ( FASB ) issued ASU 2014-09 regarding ASC Topic 606, Revenue from Contracts with Customers . The standard provides principles for recognizing revenue for the transfer of promised goods or services to customers with the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance will be effective for our fiscal year beginning February 1, 2017. Early adoption is not permitted. We are currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

In June 2014, the FASB issued ASU 2014-10, Development Stage Entities (Topic 915) . The guidance eliminates the definition of a development stage entity thereby removing the incremental financial reporting requirements from U.S. GAAP for

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development stage entities, primarily presentation of inception to date financial statements. The provisions of the amendments are effective for Ampio's calendar year 2015; however, early adoption is permitted and, accordingly, we have elected to implement the guidance in our second quarter 2014 financial statements.

In August 2014, the FASB issued Accounting Standards Update ( ASU ) No. 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ( ASU 2014-15 ). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. The amendments in this ASU are effective for reporting periods beginning after December 15, 2016, with early adoption permitted. Management is currently assessing the impact the adoption of ASU 2014-15 will have on our Condensed Financial Statements.

**Error in Classification**

Patent costs were previously classified as research and development, however, it was determined that these costs were incorrectly classified and, therefore, have been reclassified as general and administrative expense for all periods presented. Patent costs consist of legal and filing fees related to obtaining and maintaining patents and should have been excluded from research and development activities as set forth in the FASB's Accounting Standards Codification topic 730, Research and Development. The impact of the correction of this error in classification decreased research and development expenses and correspondingly increased general and administrative expenses for the three months ended September 30, 2014 and 2013 by \$555,000 and \$384,000, respectively, and for the nine months ended September 30, 2014 and 2013 by \$1,827,000 and \$1,358,000, respectively. The correction of this error had no impact on our total operating expenses or our net loss for any periods presented.

**Results of Operations September 30, 2014 Compared to September 30, 2013**

Results of operations for the three months ended September 30, 2014 (the 2014 quarter ) and the three months ended September 30, 2013 (the 2013 quarter ) reflected losses of approximately \$9,492,000 and \$6,194,000, respectively. These losses include in part non-cash charges related to stock-based compensation, derivative expense, depreciation and amortization, amortization of prepaid research and development, common stock issued for services and loss on disposal, collectively in the amount of \$2,719,000 in the 2014 quarter and \$1,142,000 in the 2013 quarter. The non-cash charges increased in the 2014 quarter primarily due to the increase in stock-based compensation associated with the hiring of new employees related to ongoing Ampion and Optina clinical trials and the new manufacturing facility.

Results of operations for the nine months ended September 30, 2014 (the 2014 period ) and the nine months ended September 30, 2013 (the 2013 period ) reflected losses of approximately \$28,896,000 and \$16,996,000, respectively. These losses include in part non-cash charges related to stock-based compensation, derivative expense, depreciation and amortization, amortization of prepaid research and development, common stock issued for services and loss on disposal, collectively in the amount of \$5,537,000 in the 2014 period and \$2,925,000 in the 2013 period. The non-cash charges increased in the 2014 period primarily due to the increase in stock-based compensation as discussed above.

**Revenue**

We have not generated material revenue in our operating history. The \$21,000 and \$13,000 license revenue recognized in the 2014 quarter and 2013 quarter, respectively, and \$55,000 and \$38,000 for the 2014 period and 2013 period respectively, represents the amortization of the upfront payments received on our license agreements. 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. The initial payment of \$250,000 from the license agreement of Zertane with a Canadian-based supplier was deferred and is being recognized over seven years.

**Table of Contents***Expenses**Research and Development*

Research and development costs are summarized as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Labor	\$ 518,000	\$ 359,000	\$ 1,397,000	\$ 1,023,000
Stock-based compensation	1,815,000	605,000	2,993,000	1,186,000
Clinical trials and sponsored research	3,533,000	3,400,000	14,696,000	8,970,000
Sponsored research - related party	66,000		144,000	
Consultants and Other	288,000	56,000	476,000	303,000
	\$ 6,220,000	\$ 4,420,000	\$ 19,706,000	\$ 11,482,000

Research and development costs consist of labor, stock-based compensation as well as drug development and clinical trials. Costs of research and development increased \$1,800,000, or 40.7%, for the 2014 quarter compared to the 2013 quarter. The increase is primarily due to stock-based compensation. Stock-based compensation increased \$1,210,000, or 200.0%, for the 2014 quarter compared to the 2013 quarter due to the incremental stock options awarded to Ampio, and Luoxis employees and the continuing vesting of awards granted in previous years. For the nine month period ended September 30, 2014 compared to the same period in 2013, costs of research and development increased \$8,224,000, or 71.6%. The increase is principally the result of clinical trials for Ampion and Optina, the Luoxis development of its ORP platform and stock-based compensation. Stock-based compensation increased \$1,807,000, or 152.4%, for the nine month period ended September 30, 2014 compared to the same period in 2013 due to the incremental stock options awarded to Ampio, Luoxis and Vyrix employees and the continuing vesting of awards granted in previous years.

*General and Administrative*

General and administrative costs are summarized as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Labor	\$ 524,000	\$ 290,000	\$ 1,692,000	\$ 775,000
Stock-based compensation	683,000	246,000	2,161,000	1,124,000
Patent costs	555,000	384,000	1,827,000	1,358,000
Professional fees	598,000	98,000	1,416,000	382,000
Occupancy, travel and other	877,000	466,000	1,976,000	1,261,000
Directors fees	62,000	52,000	190,000	142,000
	\$ 3,299,000	\$ 1,536,000	\$ 9,262,000	\$ 5,042,000



General and administrative costs increased \$1,763,000, or 114.8% for the 2014 quarter compared to the 2013 quarter. The increase is due to the costs associated with the Company initiating manufacturing and commercialization activities. The increase is also attributable to increased professional fees and stock-based compensation. For the nine month period ended September 30, 2014 general and administrative costs increased \$4,220,000, or 83.7%, compared to the same period in 2013 primarily as a result of increased professional staffing, professional fees and stock-based compensation.

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### ***Net Cash Used in Operating Activities***

During the nine month period ended September 30, 2014, our operating activities used approximately \$25.0 million in cash which was less than the net loss of \$28.9 million primarily as a result of the non-cash stock-based compensation offset by prepaid research and development related party, prepaid expenses and accounts receivable.

In the same period of 2013, the use of cash was \$14.1 million which was less than the net loss of \$17.0 million principally as a result of non-cash stock-based compensation and derivative expense.

### ***Net Cash Used in Investing Activities***

During the nine month period ended September 30, 2014, cash was used to establish our manufacturing facility and to acquire manufacturing machinery and equipment. Purchase of fixed assets increased to \$7.9 million compared to \$0.3 million for the same period in 2013, this increase reflects the purchases for Ampio's new manufacturing facility. The decrease of \$0.3 million during the nine month period ended September 30, 2014 reflects the purchase of patents for the same period in 2013.

### ***Net Cash from Financing Activities***

Net cash provided by financing activities in the nine month period ended September 30, 2014 reflects gross proceeds from the public offering of \$68.4 million offset by costs related to the offering of \$5.0 million. In the same period during 2013, net cash provided by financing activities of \$29.1 million reflects net proceeds from the registered direct placement of \$25.0 million, Luoxis private financings of \$4.0 million of net proceeds and \$0.1 million from the exercise of stock options and warrants.

### ***Liquidity and Capital Resources***

As a 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 September 30, 2014, we had cash and cash equivalents totaling \$56.8 million and \$2.8 million in accounts payable. Based upon our current expectations, we believe our capital resources at September 30, 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 the Company and its shareholders.

Our budget for 2014 reflects cash requirements for fixed, on-going expenses such as payroll, legal and accounting, patents and overhead at an average cash burn rate of approximately \$900,000 per month. The cash we raised in March 2014 is being 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 hiring of manufacturing personnel. 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 .

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### **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 have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

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 plaintiff for consulting services the plaintiff 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 Complaint also asserts claims for promissory estoppel, unjust enrichment and fraudulent inducement and concealment. In July 2014, plaintiff dismissed all claims against Dr. David Bar-Or with prejudice. In September 2014, following a five-day trial, the jury returned a defense verdict in favor of the Company and Michael Macaluso on all of the claims presented to it, specifically, plaintiff's claims for breach of contract, fraudulent inducement, and fraudulent concealment. The parties are awaiting a post-trial decision from the court on plaintiff's remaining claims for promissory estoppel and unjust enrichment. The Company believes these claims are without merit and intends to continue 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.

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

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February 14, 2014 and as amended May 23, 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.

**Item 6. Exhibits**

**Exhibit**

<b>Number</b>	<b>Description</b>
10.1	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and David Bar-Or, M.D., dated August 11, 2014 (1)
10.2	Amendment to Employment Agreement between Ampio Pharmaceuticals, Inc. and Vaughan Clift, M.D., dated August 11, 2014 (1)
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*.

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XBRL (eXtensible Business Reporting Language). The following materials from Ampio Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 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 August 15, 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.

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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**  
**Chairman and Chief Executive Officer**  
**Date: November 7, 2014**

By: /s/ Gregory A. Gould  
**Gregory A. Gould**  
**Chief Financial Officer, Treasurer and**  
**Secretary**  
**Date: November 7, 2014**