

Ampio Pharmaceuticals, Inc.  
Form 10-Q  
November 08, 2013  
**Table of Contents**

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

**FORM 10-Q**

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

**For the Quarterly Period Ended: September 30, 2013**

**or**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File No. 001-35182**

**AMPIO PHARMACEUTICALS, INC.**

**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction of**  
**incorporation or organization)**

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

**5445 DTC Parkway**  
**Suite 925**

**Greenwood Village, Colorado 80111**

**(Address of principal executive offices, including zip code)**

**(720) 437-6500**

**(Registrant's telephone number, including area code)**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer", "large accelerated filer" and "smaller reporting company" in Rule 12B-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller Reporting Company

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

As of November 8, 2013, there were 41,789,397 shares outstanding of Common Stock, par value \$0.0001, of the registrant.



**Table of Contents**

**AMPIO PHARMACEUTICALS, INC.**

**AND SUBSIDIARIES**

**NINE MONTHS ENDED SEPTEMBER 30, 2013**

**INDEX**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
Item 1. <u>Consolidated Financial Statements</u>	4
<u>Consolidated Balance Sheets as of September 30, 2013 (unaudited) and December 31, 2012</u>	4
<u>Consolidated Statements of Operations for the three and nine months ended September 30, 2013 (unaudited), the three and nine months ended September 30, 2012 (unaudited), and the period from December 18, 2008 (Inception) through September 30, 2013 (unaudited)</u>	5
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	6
<u>Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 (unaudited), the nine months ended September 30, 2012 (unaudited), and the period from December 18, 2008 (Inception) through September 30, 2013 (unaudited)</u>	7
<u>Notes to Consolidated Financial Statements (unaudited)</u>	8
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4. <u>Controls and Procedures</u>	22
<b><u>PART II OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	23
Item 1A. <u>Risk Factors</u>	23
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
Item 3. <u>Defaults Upon Senior Securities</u>	23
Item 4. <u>Mine Safety Disclosures</u>	23
Item 5. <u>Other Information</u>	23
Item 6. <u>Exhibits</u>	23
<b><u>SIGNATURES</u></b>	<b>25</b>

**Table of Contents**

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

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

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

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

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

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

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

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

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

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

*commercial developments for products that compete with our product candidates;*

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

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

*adverse developments in our research and development activities;*

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

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

*our expectations with respect to our acquisition activity.*

*In addition, there may be other factors that could cause our actual results to be materially different from the results referenced in the forward-looking statements, some of which are included elsewhere in this report, including*

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

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

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

	September 30, 2013 (Unaudited)	December 31, 2012
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 32,070,484	\$ 17,682,517
Prepaid expenses	151,179	164,890
<b>Total current assets</b>	<b>32,221,663</b>	<b>17,847,407</b>
Fixed assets, net		
In-process research and development	293,600	59,290
Patents, net	7,500,000	7,500,000
Deposits	752,654	420,468
	20,000	20,000
	8,566,254	7,999,758
<b>Total assets</b>	<b>\$ 40,787,917</b>	<b>\$ 25,847,165</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities		
Accounts payable	\$ 1,166,875	\$ 1,201,122
Deferred revenue	50,000	50,000
Warrant derivative liability	868,313	384,771
<b>Total current liabilities</b>	<b>2,085,188</b>	<b>1,635,893</b>
Long-term deferred revenue	343,750	381,250
<b>Total liabilities</b>	<b>2,428,938</b>	<b>2,017,143</b>
Commitments and contingencies (Note 6)		
Stockholders equity		
Preferred Stock, par value \$.0001; 10,000,000 shares authorized; none issued		
Common Stock, par value \$.0001; 100,000,000 shares authorized; shares issued and outstanding - 41,731,258 in 2013 and 37,009,695 in 2012	4,173	3,701

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

Additional paid-in capital	94,553,973	63,687,558
Advances to stockholders	(90,640)	(90,640)
Deficit accumulated in the development stage	(56,438,925)	(39,770,597)
<b>Total Ampio stockholders equity</b>	<b>38,028,581</b>	<b>23,830,022</b>
Non-controlling interests	330,398	
<b>Total equity</b>	<b>38,358,979</b>	<b>23,830,022</b>
Total liabilities and equity	\$ 40,787,917	\$ 25,847,165

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



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

	Three Months Ended September 30,		Nine Months Ended September 30,		December 18, 2008
	2013	2012	2013	2012	(Inception) through September 30, 2013
License revenue	\$ 12,500	\$ 12,500	\$ 37,500	\$ 37,500	\$ 106,250
Expenses					
Research and development	\$ 4,803,856	\$ 2,135,385	\$ 12,839,874	\$ 5,159,721	\$ 30,024,599
General and administrative	1,152,078	677,928	3,684,224	2,941,293	17,740,136
Total operating expenses	5,955,934	2,813,313	16,524,098	8,101,014	47,764,735
Other income (expense)					
Interest income	1,114	7,911	8,563	15,098	39,096
Interest expense					(29,317)
Unrealized loss on fair value of debt instruments					(5,547,911)
Derivative (expense) income	(251,610)	208,934	(517,477)	132,687	(3,234,977)
Total other (expense) income	(250,496)	216,845	(508,914)	147,785	(8,773,109)
Net loss, before income tax	\$ (6,193,930)	\$ (2,583,968)	\$ (16,995,512)	\$ (7,915,729)	\$ (56,431,594)
Foreign tax expense					82,500
Net loss	\$ (6,193,930)	\$ (2,583,968)	\$ (16,995,512)	\$ (7,915,729)	\$ (56,514,094)
Net loss applicable to non-controlling interests	\$ 121,851	\$	\$ 327,184	\$	\$ 327,184
Net loss applicable to Ampio	\$ (6,072,079)	\$ (2,583,968)	\$ (16,668,328)	\$ (7,915,729)	\$ (56,186,910)
Weighted average number of Ampio common shares outstanding	37,106,190	36,477,907	37,090,019	32,967,745	
Basic and diluted Ampio net loss per common share	\$ (0.16)	\$ (0.07)	\$ (0.45)	\$ (0.24)	

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



**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Consolidated Statements of Stockholders Equity (Deficit)**

	Series A Preferred Stock		Common Stock		Common Stock	Additional	Additional	Advances	Deficit	Non-controlling
	Shares	Amount	Shares	Amount	Subscribed	Paid in Capital	Issuances	to Stockholders	Accumulated in the Development Stage	Interests
8		\$		\$	\$	\$	\$	\$	\$	\$
on			1,080,000	1,080						
8			1,080,000	1,080						
on										
ion										
et			3,500,000	3,500					(252,015)	
A										
ote										
009	163,934	164				199,836				
ed										
in			7,350,000	7,350						
A										
in										
09	913,930	914				1,114,106				
					170,003					
									(1,512,908)	
er 31,										
	1,077,864	\$ 1,078	11,930,000	\$ 11,930	\$ 170,003	\$ 1,313,942	\$	\$	\$ (1,764,923)	\$
	(1,077,864)	(1,078)	3,068,958	(10,430)		11,691				

ity									
ch				7,000					
on for									
		1,078,078	108	(177,003)	1,536,522				
on		1,030,000	103		1,802,397	(3,281)			
					1,297,083				
lers						(150,183)			
							(8,053,395)		
0	\$	17,107,036	\$ 1,711	\$	\$ 5,961,635	\$ (3,281)	\$ (150,183)	\$ (9,818,318)	\$
		13,635	1		1,983,784				
on						3,281			
		1,281,852	128		9,423,947				
		1,714			3,000				
		301,604	30		109,015				
on on es, 000									
		5,167,905	517		7,852,220				
on for									
ng 8		5,092,880	509		10,916,029				
1		88,669	8		784,356				
ns		(98,416)	(9)		574,009				
		(95,700)	(9)		9				
							22,660		

on for ts		2,220,255	222		8,453,779				(18,359,234)
1 on	\$	31,081,434	\$ 3,108	\$	\$ 46,061,783	\$	\$ (127,523)	\$ (28,177,552)	\$
		24,072	3		100,147				
		680,809	68		617,932				
l,		19,520	2		32,692				
					1,522,374				
							36,883		
on for E		5,203,860	520		15,352,630				(11,593,045)
2 on	\$	37,009,695	\$ 3,701	\$	\$ 63,687,558	\$	\$ (90,640)	\$ (39,770,597)	\$
		22,752	2		88,048				
on for ts		4,600,319	460		25,003,526				
on c g					3,340,937				639,353
d) on					42,510				7,490
ts d)					(10,739)				10,739
		61,255	6		128,244				

1,	37,237	4	51,246				
			2,222,643				
d)					(16,668,328)	(327,184)	
3	\$ 41,731,258	\$ 4,173	\$ 94,553,973	\$ (90,640)	\$ (56,438,925)	\$ 330,398	

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

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

	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012	December 18, 2008 (Inception) through September 30, 2013
<b>Cash flows from operating activities:</b>			
Net loss	\$ (16,995,512)	\$ (7,915,729)	\$ (56,514,094)
Depreciation and amortization	97,319	46,797	202,266
Common stock issued for services	88,050	40,000	1,990,700
Stock-based compensation	2,222,643	822,536	7,025,885
Derivative expense (income)	517,477	(132,687)	3,234,977
Unrealized loss on fair value of debt instruments			5,547,911
Adjustments to reconcile net loss to net cash used in operating activities:			
(Increase) Decrease in prepaid expenses	13,711	(99,027)	(151,179)
Increase in related party payable			109,789
Increase (Decrease) in accounts payable	(34,247)	158,795	1,166,877
Increase (Decrease) in deferred revenue	(37,500)	(37,500)	393,750
Increase in accrued interest payable			16,948
<b>Net cash used in operating activities</b>	<b>(14,128,059)</b>	<b>(7,116,815)</b>	<b>(36,976,170)</b>
<b>Cash flows used in investing activities:</b>			
Purchase of fixed assets	(283,814)		(368,519)
Purchase of patents	(330,000)		(330,000)
Deposits			(20,000)
<b>Net cash used in investing activities</b>	<b>(613,814)</b>		<b>(718,519)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from related party notes payable and debentures			2,593,000
Proceeds from sale of common stock	25,447,318	17,542,867	66,793,742
Costs related to sale of common stock	(297,768)	(1,559,395)	(4,654,910)
Proceeds from sale of Luoxis common stock (Note 2)	4,652,500		4,652,500
Costs related to sale of Luoxis common stock (Note 2)	(672,210)		(672,210)
Proceeds from common stock subscribed			177,003
Proceeds from sales of Series A Preferred Stock			1,115,020

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

Advances (to) from shareholders		36,883		(90,640)
Payment of liabilities assumed in asset purchase				(48,515)
Payment of related party notes				(100,000)
Increase in cash from acquisition				183
Net cash provided by financing activities	29,129,840		16,020,355	69,765,173
Net change in cash and cash equivalents	14,387,967		8,903,540	32,070,484
Cash and cash equivalents at beginning of period	17,682,517		11,362,325	
Cash and cash equivalents at end of period	\$ 32,070,484	\$ 20,265,865	\$ 32,070,484	
Supplementary cash flow information:				
Interest paid	\$	\$	\$	8,358
Income taxes paid	\$	\$	\$	82,500
Non-cash transactions:				
Liabilities assumed in asset purchase, recorded as a distribution	\$	\$	\$	248,515
Conversion of notes payable to Series A Preferred Stock	\$	\$	\$	200,000
Common stock issued for common stock subscriptions received	\$	\$	\$	177,003
Deferred charge recorded for common stock issued in exchange for services	\$	\$	\$	1,802,500
Issuance of Luoxis stock for patents (Note 2)	\$ 50,000	\$	\$	50,000
Common stock issued for acquisition of DMI BioSciences, Inc.	\$	\$	\$	7,852,737
Conversion of debentures to common stock	\$	\$	\$	9,424,075
Warrant compensation from common stock offering costs	\$	\$ 180,194	\$	1,068,858
Warrant compensation from Luoxis common stock offering costs (Note 2)	\$ 313,064	\$	\$	313,064
Merger liability - shares exchanged for options	\$	\$	\$	574,000
Debenture warrant exercise fair value adjustment	\$ 33,934	\$	\$	683,499

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



---

**Table of Contents**

**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

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

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

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

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

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

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

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

*Recent Accounting Pronouncements*

In July 2013, the FASB issued ASU 2013-11, *Income Taxes (Topic 740)*. The amendment is designed to provide explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This guidance is effective for annual and interim periods beginning after December 15, 2013. The adoption of this guidance is not expected to have a significant impact on the Company's financial position or results of operations.

**Note 2 Formation of Subsidiary**

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

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

**Table of Contents**

placement agent also received 465,250 warrants to purchase Luoxis common stock valued at \$313,064 in connection with the closing, which amount has been included in total offering costs in the consolidated statement of changes in stockholders' equity (deficit). The warrants have a term of 5 years and an exercise price of \$1.00. The warrants were issuable at the final closing and exercisable one year thereafter. Concurrent with the March 15, 2013 closing, \$330,000 was paid to Trauma Research LLC and 50,000 shares of Luoxis common stock valued at \$50,000 was issued to Institute for Molecular Medicine, Inc., both related parties, for assignment of all patents previously licensed by Ampio. The patents will be amortized over an overall estimated life of 15 years.

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. The Luoxis cash balance, included in the consolidated financial statements at September 30, 2013, totaled \$2,603,479.

**Note 3 License Agreement/Revenue Recognition**

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

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

**Note 4 Derivative Financial Instruments**

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

	September 30, 2013		December 31, 2012	
	Indexed Shares	Fair Values	Indexed Shares	Fair Values
<b>Ampio's financings giving rise to derivative financial instruments:</b>				
Warrants (dates correspond to hybrid financing):				
Tranche 1 - August 10, 2010	51,215	\$ 294,482	51,215	\$ 116,635
Tranche 2 - October 22, 2010-October 29, 2010				
Tranche 3 - November 12, 2010-November 29, 2010	61,176	434,159	66,434	195,813
Tranche 4 - December 13, 2010-December 29, 2010	9,051	52,161	13,686	33,913
Tranche 5 - January 20, 2011-January 31, 2011	29,344	87,511	29,344	38,410

150,786 \$ 868,313 160,679 \$ 384,771

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

**Table of Contents**

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

	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Warrants (dates correspond to financing)				
Tranche 1 - August 10, 2010	\$ 88,442	\$ (64,288)	\$ 177,847	\$ (42,451)
Tranche 2 - October 22, 2010-October 29, 2010		(8,483)		(5,278)
Tranche 3 - November 12, 2010-November 29, 2010	125,007	(100,357)	256,117	(63,028)
Tranche 4 - December 13, 2010-December 29, 2010	14,579	(16,995)	34,412	(10,505)
Tranche 5 - January 20, 2011-January 31, 2011	23,582	(18,811)	49,101	(11,425)
	\$ 251,610	\$ (208,934)	\$ 517,477	\$ (132,687)

**Note 5 Fair Value Considerations**

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

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

Authoritative guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. The guidance establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on

market data obtained from sources independent of Ampio. Unobservable inputs are inputs that reflect our assumptions of what market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. The hierarchy is broken down into three levels based on reliability of the inputs as follows:

Level 1: Inputs that reflect unadjusted quoted prices in active markets that are accessible to Ampio for identical assets or liabilities;

Level 2: Inputs include quoted prices for similar assets and liabilities in active or inactive markets or that are observable for the asset or liability either directly or indirectly; and

Level 3: Unobservable inputs that are supported by little or no market activity.

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

**Table of Contents**

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

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
<u>September 30, 2013</u>				
<b>LIABILITIES</b>				
Warrant derivative liabilities			\$ 868,313	\$ 868,313
<u>December 31, 2012</u>				
<b>LIABILITIES</b>				
Warrant derivative liabilities			\$ 384,771	\$ 384,771

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

	September 30, 2013	December 31, 2012
<u>Warrants (All Tranches):</u>		
Exercise price	\$ 1.75	\$ 1.75
Volatility	134.53%	148.60%
Equivalent term (years)	0.07 - 0.70	0.61 - 1.08
Risk-free interest rate	0.03%	0.16%

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

	Derivative and Hybrid Debt Instruments
Balance as of December 31, 2012	\$ (384,771)
Total realized and unrealized losses:	
Included in earnings	(517,477)
Warrant exercises	33,935
Balance as of September 30, 2013	\$ (868,313)

**Note 6 Commitments and Contingencies**

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

Total	Due in Less than 1 Year	Due 1-3 Years	Due 3-5 Years	More than 5 Years
-------	----------------------------	---------------	---------------	----------------------

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

Clinical research and trial obligations	\$ 5,576,143	\$ 5,576,143	\$	\$	\$
Sponsored research agreement with related party	\$ 263,750	\$ 263,750	\$	\$	\$
Office lease	\$ 92,604	\$ 92,604	\$	\$	\$
Officers employment agreements	\$ 1,181,354	\$ 773,646	\$ 407,708	\$	\$
	\$ 7,113,851	\$ 6,706,143	\$ 407,708	\$	\$

***Clinical Research and Trial Obligations***

In connection with clinical trials for Ampion and Optina, both of which began in the first quarter of 2013, Ampio has remaining commitments of \$352,798 on contracts related to the Ampion clinical trial and \$5,171,182 on contracts related to the Optina clinical trial.



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

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

***Leases***

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

	Three Months Ended September 30,		One Months Ended September 30,	
	2013	2012	2013	2012
Rent expense	\$ 29,359	\$ 27,399	\$ 88,037	\$ 78,195

***Employment Agreements***

As of September 30, 2013, Ampio has employment agreements with four of its executive officers. Under the employment agreements, the executive officers are collectively entitled to receive \$955,000 in annual salaries. The employment agreements expired July 31, 2013 with respect to our chief scientific officer and chief regulatory affairs officer, January 2015 with respect to our chief executive officer and December 2015 with respect to our chief operating officer. The portion of the salary due to our chief scientific officer that is included in the Sponsored Research Agreement with Trauma Research LLC ( TRLLC ) is excluded from the officers' employment agreements commitment. On July 15, 2013, Ampio extended the Employment Agreements of Dr. David Bar-Or, Chief Scientific Officer, and Dr. Vaughan Clift, Chief Regulatory Affairs Officer, for one additional year, expiring July 31, 2014. In connection with this Amendment, Dr. Bar-Or and Dr. Clift were awarded 300,000 and 170,000 options, respectively, for Ampio common stock at an exercise price of \$6.15 with 50% vesting upon grant and 50% after one year.

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

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

***Shelf Registration***

On September 30, 2011, Ampio filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission to register Ampio common stock and warrants in an aggregate amount of up to \$80 million for offering from time to time in the future. The registration statement also registers for possible resale up to one million shares of common stock to be sold by directors and management (as selling shareholders) in future public offerings. On October 13, 2011 Ampio filed an amendment to identify potential selling stockholders and the number of shares they would be eligible to sell in the event of a future public offering. The shelf registration was declared effective on October 28, 2011 by the Securities and Exchange Commission. At September 30, 2013, Ampio had \$28.4 million available for future public offerings along with 714,900 shares remaining for future sale by named selling

shareholders.

***Registered Direct Placement***

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

***Underwritten Public Offering***

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

**Table of Contents****Registered Direct Offering**

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

**Private Placement Offering**

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

**Note 8 Equity Instruments****Options**

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

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

Expected volatility	70% - 89%
Risk free interest rate	0.40% - 1.40%
Expected term (years)	3.0 - 6.5
Dividend yield	0%

Ampio stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Fair Value
Outstanding December 31, 2011	3,832,874	\$ 2.75	7.31	\$ 3,443,616

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

Granted	2,095,000	\$	2.97		
Exercised	(715,476)	\$	(1.07)		
Forfeited	(256,250)	\$	(4.04)		
Expired	(33,333)	\$	(5.96)		
Outstanding December 31, 2012	4,922,815	\$	2.25	8.36	\$ 7,132,347
Granted	690,000	\$	5.52		
Exercised	(64,169)	\$	3.79		
Forfeited	(74,581)	\$	4.60		
Outstanding September 30, 2013	5,474,065	\$	2.71	7.72	\$ 8,038,668
Exercisable at September 30, 2013	4,165,176	\$	2.26	7.00	\$ 4,339,091
Available for grant at September 30, 2013	1,651,808				

**Table of Contents**

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

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

Luoxis stock option activity is as follows:

	Number of Options	Exercise Price	Remaining Contractual Life	Aggregate Fair Value
Granted June 15, 2013	1,800,000	\$ 1.00		
Outstanding September 30, 2013	1,800,000	\$ 1.00	9.72	\$ 1,272,366
Exercisable at September 30, 2013	450,000	\$ 1.00	9.72	\$ 303,492
Available for grant at September 30, 2013	3,200,000			

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Research and development expenses				
Stock options				
Ampio	\$ 554,001	\$ 135,069	\$ 932,372	\$ 310,685
Luoxis	\$ 51,584	\$	\$ 254,079	\$
General and administrative expenses				
Common stock issued for services			88,050	40,000
Stock options				

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

Ampio	217,099	155,606	892,582	511,851
Luoxis	29,156		143,610	

\$ 851,840    \$ 290,675    \$ 2,310,693    \$ 862,536

Unrecognized expense at September 30, 2013

Ampio	\$ 2,597,831
Luoxis	\$ 874,678

Weighted average remaining years to vest

Ampio	1.63
Luoxis	2.71

**Table of Contents****Warrants**

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

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding December 31, 2011	677,008	\$ 2.78	3.69
Warrants exercised - Debenture holders	(7,041)	\$ (1.75)	
Warrants exercised - Private Placement	(54,058)	\$ (3.13)	
Warrants issued in connection with Underwritten Offering	138,462	\$ 4.06	
Outstanding December 31, 2012	754,371	\$ 3.00	3.01
Warrants exercised - Debenture holders	(9,893)	\$ (1.75)	
Warrants exercised - Private/Registered Direct Placements	(57,344)	\$ (4.06)	
Outstanding September 30, 2013	687,134	\$ 2.93	2.16

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

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

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

**Note 9 Related Party Transactions**

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

In June 2013, Luoxis entered into an agreement with TRLLC, a related party controlled by Dr. David Bar-Or, a director and officer of Ampio. The agreement provides for Luoxis to pay \$5,834 per month to TRLLC in consideration for services related to research and development of the Luoxis Oxidation Reduction Potential platform. In September 2013, Luoxis entered into an addendum to the agreement which provides for Luoxis to pay an additional \$2,000 per month.

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



**Table of Contents**

**Note 10 Litigation**

On August 30, 2013, Ampio was notified of a civil complaint filed against the Company and certain of its directors and executive officers as defendants. The Complaint alleges that the defendants breached a contract with the plaintiffs for consulting services the plaintiffs purportedly provided during two time periods: in November and December 2009 in connection with a proposed reverse merger transaction, and between 2010 and 2012. The reverse merger transaction identified by the plaintiffs, and which is alleged to be the basis for contract claims, was not consummated by the Company. The plaintiffs seek an unspecified amount of compensatory damages and other relief, including 1,130,000 shares of the Company's common stock, and also assert claims for promissory estoppel, unjust enrichment and fraudulent inducement and concealment. The Company believes these claims are without merit and intends to defend this lawsuit vigorously. We believe the likelihood of a loss contingency related to this matter is remote and, therefore, no provision for a loss contingency is required.

**Note 11 Subsequent Events**

On October 4, 2013, Ampio amended the Employment Agreement of Michael Macaluso, Chief Executive Officer, to increase his annual salary from \$195,000 to \$300,000, effective October 1, 2013. As a result of Mr. Macaluso's efforts and the fact that no placement agent was used in connection with the \$25.3 million offering (See Note 7 Common Stock, Registered Direct Placement), Mr. Macaluso was also awarded a one-time bonus of \$150,000.

In preparing for the future manufacturing of Ampion, the Company, on October 10, 2013, entered into a Human Serum Albumin Ingredient Purchase and Sale Agreement (the Agreement) with a major, global manufacturer. The term of the Agreement commenced on October 10, 2013 and continues through December 31, 2018, with a 5 year extension option after 2 years. The total commitment over the period is \$11,475,000.

In connection with the interim analysis of our Optina trials for diabetic macular edema and the fact that Optina was demonstrating a beneficial anatomic effect, we initiated an open label extension study for all patients who have completed the trial. Accordingly, on October 24, 2013, we increased our contract with our clinical research organization by \$3.4 million.

## **Table of Contents**

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

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

#### **Overview**

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

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

#### **Acquisition**

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

#### **Financing History/Overview**

On February 28, 2011, we issued an aggregate of 1,281,852 shares of our common stock in retirement of the Senior Convertible Debentures issued to 21 holders of such debentures. The convertible debentures were previously issued in five tranches. The first tranche consisted of \$430,000 in principal amount issued in August 2010 to two directors and

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

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

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

## **Table of Contents**

registration was declared effective on October 28, 2011 by the Securities and Exchange Commission. At September 30, 2013 Ampio had \$28.4 million available for future public offerings along with 714,900 shares remaining for future sale by named selling shareholders.

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

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

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

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

In September 2013, we completed a registered direct placement offering for the sale of 4,600,319 shares of common stock at a price of \$5.50 per share. Our net proceeds from this offering, after deducting our estimated offering expenses, was \$25.0 million. We anticipate that we will use the net proceeds from this offering for working capital and for general corporate purposes, including continuation and completion of our Ampion and Optina clinical trials, potential submission of a BLA relating to Ampion and a NDA relating to Optina, acquisition of manufacturing equipment and related outfitting in connection with the leasing of a new manufacturing facility and the potential hiring of additional personnel to manufacture Ampion.

## **Product Update**

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

### ***Ampion for Osteoarthritis of the Knee***

On August 14, 2013 and September 30, 2013, we announced results of the SPRING study of Ampion for the treatment of osteoarthritis of the knee. The SPRING study was a U.S. multicenter randomized (1:1:1:1), double-blind, vehicle controlled trial designed to evaluate the safety and efficacy of Ampion in osteoarthritis of the knee patients. 329 patients were randomized to receive one of two doses (4 mL or 10 mL) of Ampion or corresponding saline control via intra-articular injection. The primary study objective was to evaluate the relative efficacy of Ampion 4 mL versus

Ampion 10 mL. The primary endpoint was mean change in pain as measured on the WOMAC, a standardized scoring metric for pain, from baseline for Ampion compared to the same volume of saline. Secondary endpoints included evaluating safety and quality of life, as well as stiffness and function. Ampion dose cohorts experienced statistically significant reductions in pain compared to control. There were no significant differences between the efficacy of the two Ampion doses. Selection of the optimal dose for the Phase III pivotal trial will be decided in consultation with the FDA. A brief summary of the combined Ampion topline results is as follows:

Patients receiving Ampion achieved significantly greater reduction in pain (WOMAC A) from baseline to 12 weeks compared to saline vehicle control ( $p = 0.0038$ ) and over the whole period of 12 weeks ( $p = 0.01$ )

Clinical efficacy defined as pain reduction was evident as early as four weeks after the injection ( $p = 0.025$ ) and continued to show improvement through 12 weeks ( $p = 0.0038$ )

Patients receiving Ampion experienced, on average, a 42.3% reduction in pain from baseline

Kellgren-Lawrence IV patients receiving Ampion achieved significantly greater reduction in pain (WOMAC A) from baseline to 12 weeks compared to saline vehicle control ( $p = 0.017$ )

Patients receiving Ampion achieved significantly greater improvement in function (WOMAC C) from baseline to 12 weeks compared to saline vehicle control ( $p = 0.044$ )

Patients receiving Ampion also demonstrated significantly greater improvement in overall quality of life measures (Patient Global Assessment) from baseline to 12 weeks compared to saline vehicle control ( $p = 0.012$ )

Ampion was well tolerated with minimal adverse events (AEs) reported in the study. AEs were well balanced between Ampion and control groups. There were no drug-related serious adverse events (SAEs)

## **Table of Contents**

Subsequently, we released 20 week data from the 4 mL cohort of the SPRING trial including patients rated Kellgren-Lawrence grade 3 or grade 4 as determined at the time of initial screening. We excluded patients rated Kellgren-Lawrence grade 2 for this particular sub-population analyses in order to highlight results in patients with moderate to severe osteoarthritis of the knee. The SPRING trial extension to week 20 was not defined a priori, and therefore the 4 mL patient cohort included 97 patients in the extension study, 66% of which were Kellgren-Lawrence grade 3 or 4.

50% of patients receiving Ampion were considered responders at week 20 compared to 25% in the vehicle control group ( $p = 0.04$ ). Patients were considered responders if they achieved 40% or greater improvement in pain (WOMAC A) and function (WOMAC C).

Patients receiving Ampion achieved significantly greater reduction in pain (WOMAC A) from baseline to 20 weeks compared to saline vehicle control ( $p = 0.02$ ) and over the whole period of 20 weeks ( $p = 0.005$ )

Patients receiving Ampion achieved significantly greater improvement in function (WOMAC C) from baseline to 20 weeks compared to saline vehicle control ( $p = 0.05$ ) and over the whole period of 20 weeks ( $p = 0.04$ )

On October 29, 2013, we presented and discussed the Ampion clinical data with the FDA in a Type B pre-BLA (Biologics License Application) meeting that was informative and constructive. The formal response from the FDA in regards to what activities will be required to complete the BLA process is typically received within 30 days of the pre-BLA meeting and we await their guidance.

On October 10, 2013, we entered into a Human Serum Albumin Ingredient Purchase and Sale Agreement (the Agreement) with a major, global manufacturer, which will provide a long term dedicated supply of human serum albumin (the Product). Under the Agreement, the Company has agreed to purchase a pre-determined quantity of the Product sufficient for Ampio to serve the osteoarthritis patient population currently undergoing treatment. The agreement sets minimum and maximum annual quantities that may be purchased but it enables Ampio to increase such maximum with notice, so Ampio should not be limited in its ability to treat additional patient populations where the anti-inflammatory capabilities of Ampion may show clinical benefit. The term of the Agreement commenced on October 10, 2013 and continues through December 31, 2018. The total commitment by the Company over the period is \$11,475,000. The term of the Agreement may be extended 5 additional years at the completion of the second year by written agreement of both parties. The Agreement provides for early termination by advance written notice or for uncured breach as well as representations, warranties and indemnity obligations customary for agreements of this type.

### ***Optina for Diabetic Macula Edema***

On October 7, 2013, we received positive results from the interim analysis of Optina trial for diabetic macular edema. After review of the interim data from the ongoing study, it was determined that there was a treatment dosage that was demonstrating a potentially beneficial anatomic effect. Given that there were no significant safety concerns identified in the study to date, a recommendation to continue the trial was made. This allowed the immediate initiation of an open label extension study using the optimum dose of Optina for all patients who have completed the trial and wish to continue treatment for an additional 12 weeks.

***ORP, Point-of-Care Diagnostic Device***

On October 1, 2013 Luoxis Diagnostics announced results from a recently completed clinical study of patients with isolated traumatic brain injury ( iTBI ). This study demonstrated statistically significant correlations between Oxidation Reduction Potential ( ORP ) and the severity of injury among iTBI patients. ORP is measured using the company s proprietary RedoxSYS diagnostic system, a point-of-care diagnostic system enabling rapid analysis of multiple markers of oxidative stress. Increases in plasma static Oxidation Reduction Potential (spot measurement, sORP) levels were consistently shown to closely correlate with increases in iTBI severity as measured by the Abbreviated Injury Score (p=0.02). The Company also announced the issuance of its third US patent (US patent number 8,512,548) for the RedoxSYS diagnostic system.

**Known Trends or Future Events**

We have not generated any significant revenues and have therefore incurred significant net losses totaling \$56.2 million since our inception in December 2008. The assets we purchased from BioSciences in April 2009 generated minimal revenues prior to their acquisition. Although we have raised capital in the past and raised net proceeds of \$29.0 million, \$15.4 million and \$19.4 million through the sale of common stock in 2013, 2012 and 2011, respectively, we cannot assure you that we will be able to secure such additional financing, if needed, or that it will be adequate to execute our business strategy. Even if we obtain additional financing, it may be costly and may require us to agree to covenants or other provisions that will favor new investors over existing shareholders.



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

---

**Table of Contents**

**Significant Accounting Policies and Estimates**

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

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

**Results of Operations    September 30, 2013 Compared to September 30, 2012**

Results of operations for the three months ended September 30, 2013 (the 2013 quarter ) and the three months ended September 30, 2012 (the 2012 quarter ) reflected losses of approximately \$6,194,000 and \$2,584,000, respectively. These losses include non-cash income and charges related to derivative income/expense, stock-based compensation, common stock issued for services and depreciation and amortization in the amount of \$1,142,000 in the 2013 quarter and \$97,300 in the 2012 quarter.

Results of operations for the nine months ended September 30, 2013 (the 2013 period ) and the nine months ended September 30, 2012 (the 2012 period ) reflected losses of approximately \$16,995,000 and \$7,916,000, respectively. These losses include non-cash charges related to derivative expense/income, stock-based compensation, common stock issued for services and depreciation and amortization in the amount of \$2,925,000 in the 2013 period and \$777,000 in the 2012 period.

***Revenue***

We are a development stage enterprise and have not generated material revenue in our operating history. The \$37,500 license revenue recognized in the 2013 period and 2012 period represents the amortization of the upfront payment received on our license agreement. The initial payment of \$500,000 from the license agreement of Zertane with a Korean pharmaceutical company was deferred and is being recognized over 10 years.

***Expenses***

***Research and Development***

Research and development costs are summarized as follows:

Three Months Ended September 30, Nine Months Ended September 30,

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

	2013	2012	2013	2012
Labor	\$ 359,000	\$ 387,000	\$ 1,023,000	\$ 1,120,000
Patent costs	384,000	416,000	1,358,000	1,092,000
Stock-based compensation	605,000	135,000	1,186,000	311,000
Clinical trials and sponsored research	3,400,000	1,159,000	8,970,000	2,357,000
Consultants	55,000	38,000	302,000	280,000
	\$ 4,803,000	\$ 2,135,000	\$ 12,839,000	\$ 5,160,000

Research and development costs consist of labor, research and development of patents and intellectual property, stock-based compensation as well as drug development and clinical trials. Costs of research and development increased \$2,668,000, or 125%, for the 2013 quarter compared to the 2012 quarter and \$7,679,000, or 149%, for the 2013 period compared to the 2012 period. The increases are principally the result of clinical trials for Ampion and Optina, and the Luoxis development of its ORP platform. Stock-based compensation increased due to the incremental stock options awarded in both Ampio and Luoxis and the continuing vesting of awards granted in previous years.

**Table of Contents***General and Administrative*

General and administrative costs are summarized as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Labor	\$ 290,000	\$ 172,000	\$ 775,000	\$ 1,083,000
Stock-based compensation	246,000	156,000	1,124,000	552,000
Professional fees	98,000	50,000	382,000	283,000
Occupancy, travel and other	466,000	245,000	1,261,000	838,000
Directors fees	52,000	55,000	142,000	185,000
	\$ 1,152,000	\$ 678,000	\$ 3,684,000	\$ 2,941,000

General and administrative costs increased \$474,000, or 70%, for the 2013 quarter compared to the 2012 quarter. The increases are primarily due to increased professional staffing in Luoxis, stock option awards granted by Luoxis and continuing vesting of Ampio awards granted in previous years, and occupancy, travel and other. These other expenses also include insurance and investor relations.

For the 2013 period, general and administrative costs increased \$743,000, or 25%, compared to the 2012 period primarily as a result of increases in stock-based compensation and occupancy, travel and other which were off-set by a reduction in labor due to a first quarter 2012 one-time payout to our former CEO pursuant to the terms of the employment agreement.

*Derivative (expense) income*

We recorded \$251,610 of non-cash derivative expense in the 2013 quarter compared to \$208,934 of non-cash derivative income in the 2012 quarter and \$517,477 of non-cash derivative expense in the 2013 period compared to \$132,687 of non-cash derivative income in the 2012 period in connection with our hybrid financial instruments consisting of debentures and related warrants. These amounts relate to the subsequent changes in fair value of the debentures issued in 2011 and 2010 stemming from the embedded derivative features (conversion options, down-round protection and mandatory conversion provisions) and the changes in fair value of warrants issued in conjunction with the debentures.

*Net Cash Used in Operating Activities*

During the 2013 period, our operating activities used approximately \$14.1 million in cash which was less than the net loss of \$16.7 million primarily as a result of the non-cash stock based compensation and derivative expense.

In the 2012 period, the use of cash was \$7.1 million and was approximately the same as the \$7.9 million net loss principally as a result of non-cash stock-based compensation being off-set by changes in prepaid expense and accounts payable.

*Net Cash Used in Investing Activities*

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

***Net Cash from Financing Activities***

Net cash provided by financing activities in the 2013 period of \$29.1 million reflects proceeds from the registered direct placement of \$25.0 million, Luoxis private financings of \$4.0 million and \$0.1 million from the exercise of stock options and warrants.

In the 2012 period, net cash provided by financing activities was \$16 million. During the period, Ampio completed an underwritten public offering, with net proceeds of \$15.4 million, exercise of stock options and warrants of \$630,000 and repayment of \$37,000 related to stockholder advances made in 2010.

---

**Table of Contents*****Liquidity and Capital Resources***

As a development stage biopharmaceutical company, we have not generated significant revenue as our primary activities are focused on research and development, advancing our primary product candidates, and raising capital. As of September 30, 2013, we had cash and cash equivalents totaling \$32.1 million and \$1.2 million in accounts payable, of which \$2.6 million of the cash and cash equivalents and \$0.2 million in payables related to Luoxis. Based upon our current expectations, we believe our capital resources at September 30, 2013 will be sufficient to fund our currently planned operations into the first quarter of 2015. This estimate is based on a number of assumptions that may prove to be wrong, and we could exhaust our available cash and cash equivalents earlier than presently anticipated. We may be required or choose to seek additional capital to expand our clinical development activities for Ampion and Optina. This could be necessary either assuming positive results of our ongoing clinical trials or if we face challenges or delays in connection with those trials. Additional funding will be required for the commercial launch of Ampion and Optina. We also may choose to seek additional capital to maintain minimum cash balances that we deem reasonable and prudent. We intend to evaluate the capital markets from time to time to determine whether to raise additional capital in the form of equity, convertible debt or otherwise, depending on market conditions relative to our need for funds at such time, and we may seek to raise additional capital should we conclude that such capital is available on terms that we consider to be in the best interests of us and our stockholders.

We have prepared a budget for 2013 which reflects cash requirements for fixed, on-going expenses such as payroll, legal and accounting, patents and overhead at an average cash burn rate of between \$550,000 and \$600,000 per month. As of September 30, 2013 additional funds in the amount of approximately \$5.6 million are planned for regulatory approvals and completion of clinical trials in 2013. The cash we raised in September 2013 will be used for working capital and general corporate purposes including continuation and completion of our Ampion and Optina clinical trials, potential submission of a BLA relating to Ampion and a NDA relating to Optina, acquisition of manufacturing equipment, leasing of a new manufacturing facility and the potential 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.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

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

foregoing risks and therefore currently engages in no hedging activities.

**Item 4. Controls and Procedures.**

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

**Changes in Internal Control over Financial Reporting**

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

**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings.**

On August 30, 2013, Ampio became aware of a civil complaint filed in the District Court for Arapahoe County, Colorado on or about August 28, 2013 (the Complaint). The Complaint names the Company and certain of its directors and executive officers as defendants. The Complaint alleges that the defendants breached a contract with the plaintiffs for consulting services the plaintiffs purportedly provided during two time periods: in November and December 2009 in connection with a proposed reverse merger transaction, and between 2010 and 2012. The reverse merger transaction identified by the plaintiffs and which is alleged to be the basis for contract claims was not consummated by the Company. The plaintiffs seek an unspecified amount of compensatory damages and other relief, including 1,130,000 share of the Company common stock, and also assert claims for promissory estoppel, unjust enrichment and fraudulent inducement and concealment. The Company believes these claims are without merit and intends to defend this lawsuit vigorously.

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

**Item 1A. Risk Factors.**

Certain factors exist which may affect the Company's business and could cause actual results to differ materially from those expressed in any forward-looking statements. The Company has not experienced any material changes from those risk factors as previously disclosed in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2013. However, the Company will continue to require additional capital, the receipt of which is not assured. Also, the Company currently plans to design, develop, and create its own manufacturing facility which would manufacture Ampion for registration, batching and future clinical supply as well as commercial supply. If we experience delays or difficulties in this effort, the Company's clinical trials may be impacted, its development and commercialization efforts may be impeded 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**

**Number Description**

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

**Table of Contents**

- \* The certification attached as Exhibit 32.1 accompanying this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, shall not be deemed filed by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.
- + Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

Table of Contents

**SIGNATURES**

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

AMPIO PHARMACEUTICALS, INC.

By: /s/ Michael Macaluso  
**Michael Macaluso**  
**Chief Executive Officer**  
**Date: November 8, 2013**

By: /s/ Mark D. McGregor  
**Mark D. McGregor**  
**Chief Financial Officer**  
**Date: November 8, 2013**